EXHIBIT F

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Attorneys for Plaintiffs
EDGE SYSTEMS CORPORATION
AXIA MEDSCIENCES, LLC

IN THE UNITED STATES DISTRICT COURT

FOR THE CENTRAL DISTRICT OF CALIFORNIA

EDGE SYSTEMS CORPORATION, a California corporation, and AXIA MEDSCIENCES, LLC,, a Delaware limited liability company, Plaintiffs, v. BIO-THERAPEUTIC, INC., a Washington corporation, Defendant.	Civil Action No. CV 11-04993 JFW (AGRx) COMPLAINT FOR PATENT INFRINGEMENT DEMAND FOR JURY TRIAL

Plaintiffs Edge Systems Corporation ("Edge") and Axia MedSciences, LLC ("Axia"), for their Complaint against Defendant Bio-Therapeutic, Inc. ("BT"), allege as follows:

PARTIES

1. Plaintiff Edge is a California corporation having a principal place of business at 2277 Redondo Avenue, Signal Hill, California, 90755.

2. Edge manufactures spa and skin treatment products, including Edge's Hydrafacial and Delphia microdermabrasion systems, and sells and distributes them throughout the United States, including in this Judicial District.

3. Plaintiff Axia is a Delaware limited liability company having a principal place of business at 23 Hallmark Circle, Menlo Park, California, 94025.

4. Upon information and belief, Defendant BT is a corporation organized and existing under the laws of the state of Washington, having a principal place of business at 2244 1st Avenue South, Seattle, Washington, 98134.

JURISDICTION AND VENUE

5. This action arises under the Patent Laws of the United States, 35 U.S.C. §§ 100, *et seq.*

6. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a).

7. Upon information and belief, BT conducts business throughout the United States, including in this Judicial District, and has committed the acts complained of in this Judicial District and elsewhere.

8. This Court has personal jurisdiction over BT by virtue of its systematic and continuous contacts with California and by virtue of its actions in California, including in this Judicial District, constituting infringement of the patents in suit.

9. Venue is proper in this Judicial District pursuant to 28 U.S.C. § 1391(b), (c) and 1400(b), and by Plaintiffs' choice of venue.

FIRST CLAIM FOR RELIEF

INFRINGEMENT OF U.S. PATENT NO. 6,641,591

10. Plaintiffs incorporate by reference and reallege each of the allegations set forth in Paragraphs 1-9 above.

11. On November 4, 2003, U.S. Patent No. 6,641,591 ("the '591 Patent"), entitled "INSTRUMENTS AND TECHNIQUES FOR CONTROLLED REMOVAL OF EPIDERMAL LAYERS," was duly and legally issued by the United States Patent and Trademark Office. Axia is the owner by assignment of all right and title, both legal and equitable, to the '591 Patent. A copy of the '591 Patent is attached hereto as Exhibit 1.

12. Edge is the exclusive licensee of the '591 Patent.

13. Edge has provided proper and sufficient notice to the public that its products are patented under the '591 Patent by marking its products with the patent number.

14. Upon information and belief, BT manufactures, distributes, imports, offers to sell, and/or sells in the United States certain spa and skin treatment products that infringe the '591 Patent, including but not limited to, the BT Bio-Hydroderm microdermabrasion system and accessories, the BT Bio-Hydrotip microdermabrasion system and accessories, and the BT AQUAFUSE microdermabrasion system and accessories.

15. Upon information and belief, BT has contributed to the infringement of the '591 Patent by others, through BT's activities relating to its spa and skin treatment products, including but not limited to, the BT Bio-Hydroderm microdermabrasion system and accessories, the BT Bio-Hydrotip microdermabrasion system and accessories, and the BT AQUAFUSE microdermabrasion system and accessories.

16. Upon information and belief, BT has induced infringement of the '591 Patent by others, through BT's activities relating to its spa and skin treatment products, including but not limited to, the BT Bio-Hydroderm microdermabrasion system and accessories, the BT Bio-Hydrotip microdermabrasion system and accessories, and the BT AQUAFUSE microdermabrasion system and accessories.

17. Each of BT's infringing activities is without the consent of, authority of, or license from Plaintiffs.

18. On April 15, 2011, Edge's attorney sent a cease and desist letter to David Suzuki, President of BT, informing him of Edge's rights to the '591 Patent and that BT's activities relating to the BT Bio-Hydroderm microdermabrasion system and accessories, the BT Bio-Hydrotip microdermabrasion system and accessories, and the BT AQUAFUSE microdermabrasion system and accessories, infringed the '591 Patent. A copy of that letter is attached hereto as Exhibit 4.

19. On May 19, 2011, after receiving no substantive response, Edge's attorney sent a follow-up letter, again warning BT of patent infringement. A copy of that letter is attached hereto as Exhibit 5.

20. To date, Edge has not received any substantive response from BT concerning infringement of the '591 Patent.

21. BT's acts of infringement have caused damage to Plaintiffs in an amount to be determined at trial.

22. BT's infringement of the '591 Patent is causing irreparable harm to Plaintiffs, for which there is no adequate remedy at law. BT's infringement will continue, and will continue to cause irreparable harm to Plaintiffs, unless BT's infringement is enjoined by this Court.

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23. Upon information and belief, BT's infringement of the '591 Patent was and is willful and deliberate, entitling Plaintiffs to enhanced damages under 35 U.S.C. § 284 and attorneys' fees and non-taxable costs under 35 U.S.C. § 285.

SECOND CLAIM FOR RELIEF

INFRINGEMENT OF U.S. PATENT NO. 7,678,120

24. Plaintiffs incorporate by reference and reallege each of the allegations set forth in Paragraphs 1-23 above.

25. On March 16, 2010, U.S. Patent No. 7,678,120 ("the '120 Patent"), entitled "INSTRUMENTS AND TECHNIQUES FOR CONTROLLED REMOVAL OF EPIDERMAL LAYERS," was duly and legally issued by the United States Patent and Trademark Office. Axia is the owner by assignment of all right and title, both legal and equitable, to the '120 Patent. A copy of the '120 Patent is attached hereto as Exhibit 2.

26. Edge is the exclusive licensee of the '120 Patent.

27. Upon information and belief, BT manufactures, distributes, imports, offers to sell, and/or sells in the United States certain spa and skin treatment products that infringe the '120 Patent, including but not limited to, the BT Bio-Hydroderm microdermabrasion system and accessories, the BT Bio-Hydrotip microdermabrasion system and accessories, and the BT AQUAFUSE microdermabrasion system and accessories.

28. Upon information and belief, BT has contributed to the infringement of the '120 Patent by others, through BT's activities relating to its spa and skin treatment products, including but not limited to, the BT Bio-Hydroderm microdermabrasion system and accessories, the BT Bio-Hydrotip microdermabrasion system and accessories, and the BT AQUAFUSE microdermabrasion system and accessories.

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29. Upon information and belief, BT has induced infringement of the '120 Patent by others, through BT's activities relating to its spa and skin treatment products, including but not limited to, the BT Bio-Hydroderm microdermabrasion system and accessories, the BT Bio-Hydrotip microdermabrasion system and accessories, and the BT AQUAFUSE microdermabrasion system and accessories.

30. Each of BT's infringing activities is without the consent of, authority of, or license from Plaintiffs.

31. On April 15, 2011, Edge's attorney sent a cease and desist letter to David Suzuki, President of BT, informing him of Edge's rights to the '120 Patent and that BT's activities relating to the BT Bio-Hydroderm microdermabrasion system and accessories, the BT Bio-Hydrotip microdermabrasion system and accessories, and the BT AQUAFUSE microdermabrasion system and accessories, infringed the '120 Patent. A copy of that letter is attached hereto as Exhibit 4.

32. On May 19, 2011, after receiving no substantive response, Edge's attorney sent a follow-up letter, again warning BT of patent infringement. A copy of that letter is attached hereto as Exhibit 5.

33. To date, Edge has not received any substantive response from BT concerning infringement of the '120 Patent.

34. BT's acts of infringement have caused damage to Plaintiffs in an amount to be determined at trial.

35. BT's infringement of the '120 Patent is causing irreparable harm to Plaintiffs, for which there is no adequate remedy at law. BT's infringement will continue, and will continue to cause irreparable harm to Plaintiffs, unless BT's infringement is enjoined by this Court.

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36. Upon information and belief, BT's infringement of the '120 Patent was and is willful and deliberate, entitling Plaintiffs to enhanced damages under 35 U.S.C. § 284 and attorneys' fees and non-taxable costs under 35 U.S.C. § 285.

THIRD CLAIM FOR RELIEF

INFRINGEMENT OF U.S. PATENT NO. 7,789,886

37. Plaintiffs incorporate by reference and reallege each of the allegations set forth in Paragraphs 1-36 above.

38. On March 16, 2010, U.S. Patent No. 7,789,886 ("the '886 Patent"), entitled "INSTRUMENTS AND TECHNIQUES FOR CONTROLLED REMOVAL OF EPIDERMAL LAYERS," was duly and legally issued by the United States Patent and Trademark Office. Axia is the owner by assignment of all right and title, both legal and equitable, to the '886 Patent. A copy of the '886 Patent is attached hereto as Exhibit 3.

39. Edge is the exclusive licensee of the '886 Patent.

40. Upon information and belief, BT manufactures, distributes, imports, offers to sell, and/or sells in the United States certain spa and skin treatment products that infringe the '886 Patent, including but not limited to, the BT Bio-Hydroderm microdermabrasion system and accessories, the BT Bio-Hydrotip microdermabrasion system and accessories, and the BT AQUAFUSE microdermabrasion system and accessories.

41. Upon information and belief, BT has contributed to the infringement of the '886 Patent by others, through BT's activities relating to its spa and skin treatment products, including but not limited to, the BT Bio-Hydroderm microdermabrasion system and accessories, the BT Bio-Hydrotip microdermabrasion system and accessories, and the BT AQUAFUSE microdermabrasion system and accessories.

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42. Upon information and belief, BT has induced infringement of the '886 Patent by others, through BT's activities relating to its spa and skin treatment products, including but not limited to, the BT Bio-Hydroderm microdermabrasion system and accessories, the BT Bio-Hydrotip microdermabrasion system and accessories, and the BT AQUAFUSE microdermabrasion system and accessories.

43. Each of BT's infringing activities is without the consent of, authority of, or license from Plaintiffs.

44. On April 15, 2011, Edge's attorney sent a cease and desist letter to David Suzuki, President of BT, informing him of Edge's rights to the '886 Patent and that BT's activities relating to the BT Bio-Hydroderm microdermabrasion system and accessories, the BT Bio-Hydrotip microdermabrasion system and accessories, and the BT AQUAFUSE microdermabrasion system and accessories, infringed the '886 Patent. A copy of that letter is attached hereto as Exhibit 4.

45. On May 19, 2011, after receiving no substantive response, Edge's attorney sent a follow-up letter, again warning BT of patent infringement. A copy of that letter is attached hereto as Exhibit 5.

46. To date, Edge has not received any substantive response from BT concerning infringement of the '886 Patent.

47. BT's acts of infringement have caused damage to Plaintiffs in an amount to be determined at trial.

48. BT's infringement of the '886 Patent is causing irreparable harm to Plaintiffs, for which there is no adequate remedy at law. BT's infringement will continue, and will continue to cause irreparable harm to Plaintiffs, unless BT's infringement is enjoined by this Court.

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49. Upon information and belief, BT's infringement of the '886 Patent was and is willful and deliberate, entitling Plaintiffs to enhanced damages under 35 U.S.C. § 284 and attorneys' fees and non-taxable costs under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for judgment and seek relief as follows:

A. A judgment that BT has infringed U.S. Patent Nos. 6,641,591, 7,678,120, and 7,789,886;

B. Preliminary and permanent injunctions against further infringement by BT of U.S. Patent Nos. 6,641,591, 7,678,120, and 7,789,886, including injunctions against direct infringement, contributory infringement, and induced infringement;

C. An award of damages for BT's infringement of U.S. Patent Nos. 6,641,591, 7,678,120, and 7,789,886;

D. A declaration that BT's infringement of U.S. Patent Nos. 6,641,591, 7,678,120, and 7,789,886 was and is willful, and that this is an exceptional case under 35 U.S.C. § 285;

E. A trebling of the award of damages under 35 U.S.C. § 284, or such other enhancement of the award of damages that the Court deems appropriate;

F. An award of attorneys' fees and non-taxable costs under 35 U.S.C. § 285 on account of BT's willful infringement;

G. An award of taxable costs; and

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H. Such other and further relief as this Court may deem just and proper.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: June 10, 2011

By: _____
Brenton R. Babcock
Kent Shum
Attorneys for Plaintiffs
EDGE SYSTEMS CORPORATION
AXIA MEDSCIENCES, LLC

DEMAND FOR JURY TRIAL

Pursuant to Rule 38(b) of the Federal Rules of Civil Procedure, Plaintiffs Edge Systems Corporation and Axia MedSciences, LLC demand a trial by jury of all issues raised by the pleadings which are triable by jury.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: JUNE 10, 2011 By: _____

Brenton R. Babcock
Kent Shum
Attorneys for Plaintiffs
EDGE SYSTEMS CORPORATION
AXIA MEDSCIENCES, LLC

11404974

EXHIBIT 1

US006641591B1

(12) **United States Patent**
Shadduck

(10) **Patent No.: US 6,641,591 B1**
(45) **Date of Patent: Nov. 4, 2003**

(54) **INSTRUMENTS AND TECHNIQUES FOR CONTROLLED REMOVAL OF EPIDERMAL LAYERS**

(76) Inventor: **John H. Shadduck**, 1490 Vistazo West, Tiburon, CA (US) 94920

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **09/648,025**

(22) Filed: **Aug. 25, 2000**

Related U.S. Application Data

(60) Provisional application No. 60/150,782, filed on Aug. 26, 1999.

(51) **Int. Cl.**[7] **A61B 17/50**
(52) **U.S. Cl.** **606/131**
(58) **Field of Search** 606/1, 137, 133, 606/131, 132, 79, 170, 171, 180; 604/289, 290, 313, 315; 608/133, 53, 80

(56) **References Cited**

U.S. PATENT DOCUMENTS

5,759,185 A * 6/1998 Grinberg 606/180
6,139,554 A * 10/2000 Karkar et al. 606/131
6,162,232 A * 12/2000 Shadduck 604/289
6,183,483 B1 * 2/2001 Chang 606/131
6,241,739 B1 * 6/2001 Waldron 606/131

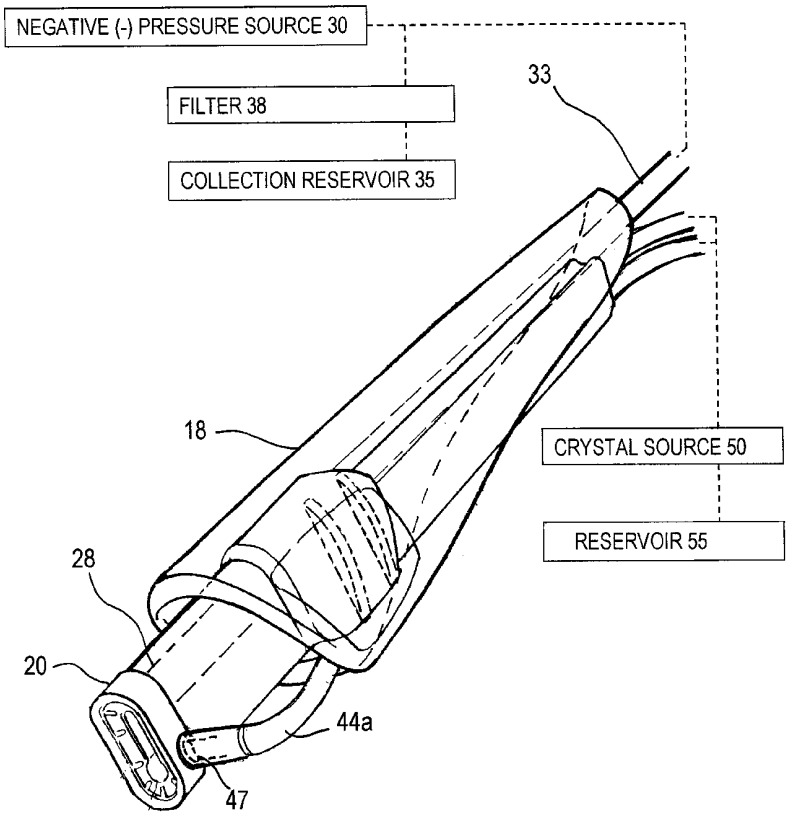
* cited by examiner

Primary Examiner—Michael J. Milano
Assistant Examiner—Vy Q. Bui

(57) **ABSTRACT**

An instrument and technique for the removal of epidermal layers in a controlled manner utilizing a hand-held instrument with a working end that (i) a vacuum aspiration system, (ii) a source for delivery of a sterile fluids or pharmacological agents to the skin; and (iii) a skin interface surface in the working end that has specially shape structure for abrading surface layers of the patient's epidermis as the working end is moved over the patient's skin while at the same time causing rapid penetration of the fluids into the skin for therapeutic purposes. Movement of the working end across the skin causes abrasion of the surface layers in a path over the patient's skin. The method of the invention may be used in a periodic treatment for the removal of superficial skin layers that enhances the synthesis of dermal collagen aggregates by inducing the body's natural wound healing response. The method of the invention creates more normal dermal architectures in skin with limited depths of skin removal by the series of superficial treatments that may be comparable to the extent of neocollagenesis caused by a deep skin removal treatment (e.g., CO_2 laser skin removal).

17 Claims, 9 Drawing Sheets



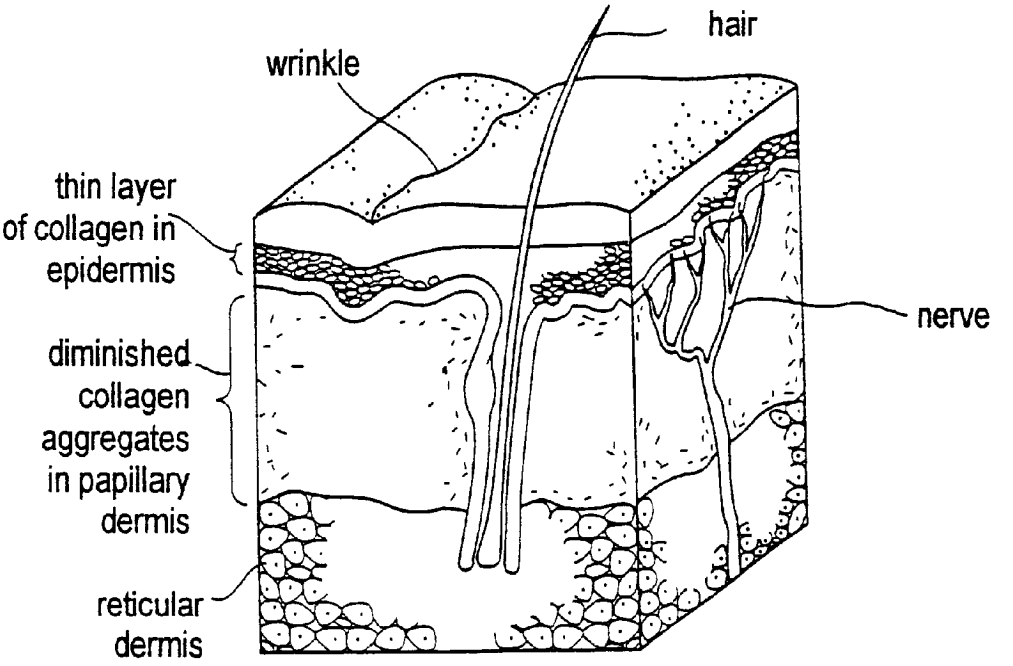

hair
wrinkle
thin layer of collagen in epidermis
nerve
diminished collagen aggregates in papillary dermis
reticular dermis

FIG. 1A

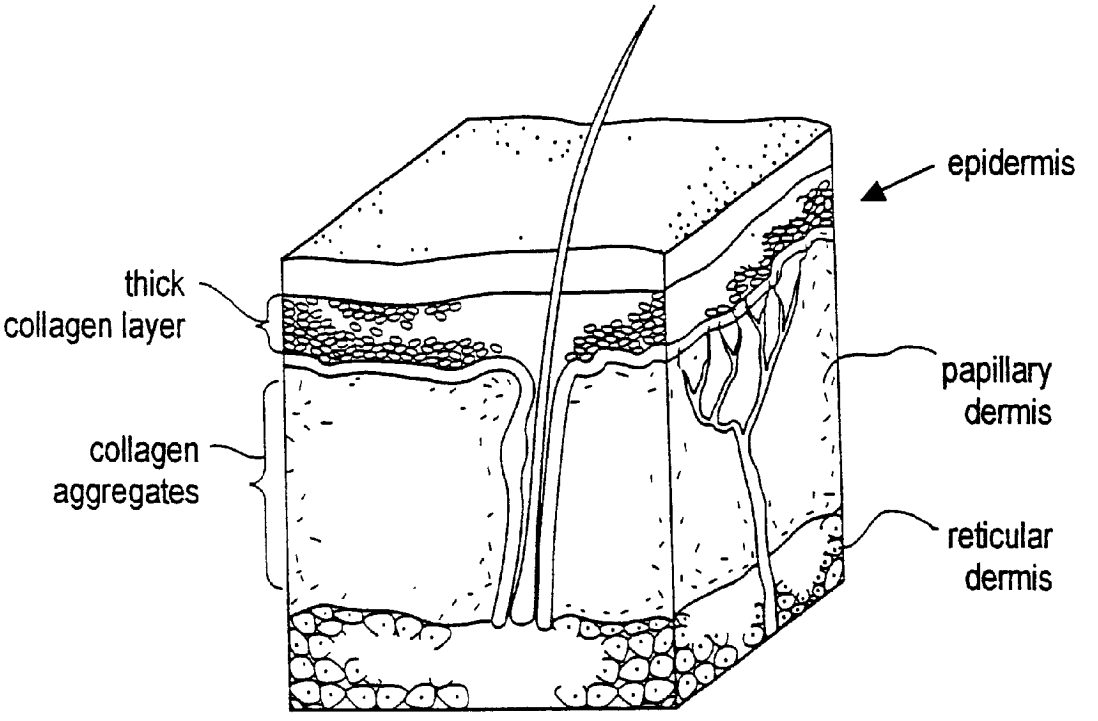

epidermis
thick collagen layer
papillary dermis
collagen aggregates
reticular dermis

FIG. 1B

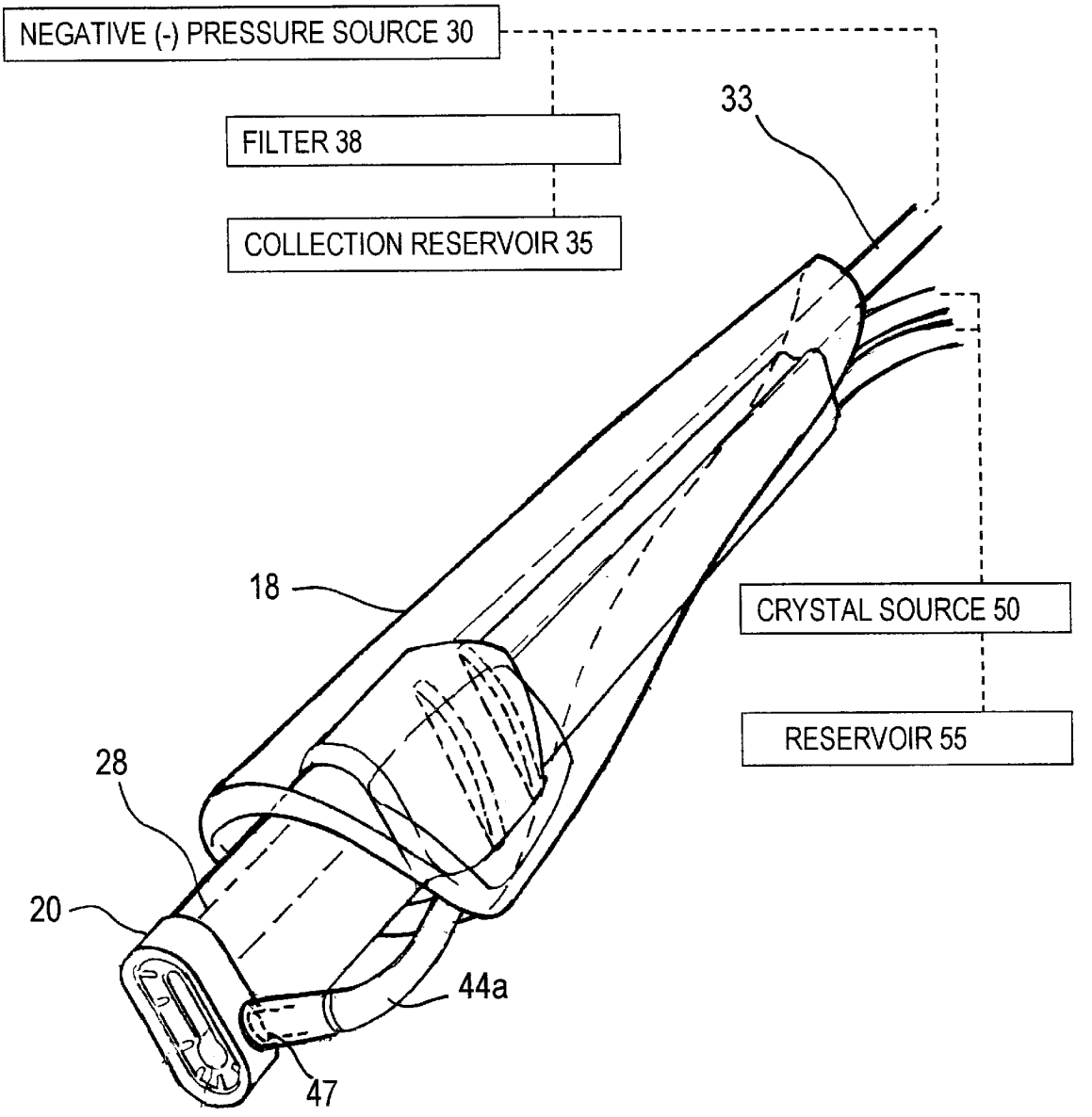

NEGATIVE (-) PRESSURE SOURCE 30
FILTER 38
COLLECTION RESERVOIR 35
33
18
CRYSTAL SOURCE 50
RESERVOIR 55
28
20
44a
47

FIG. 2

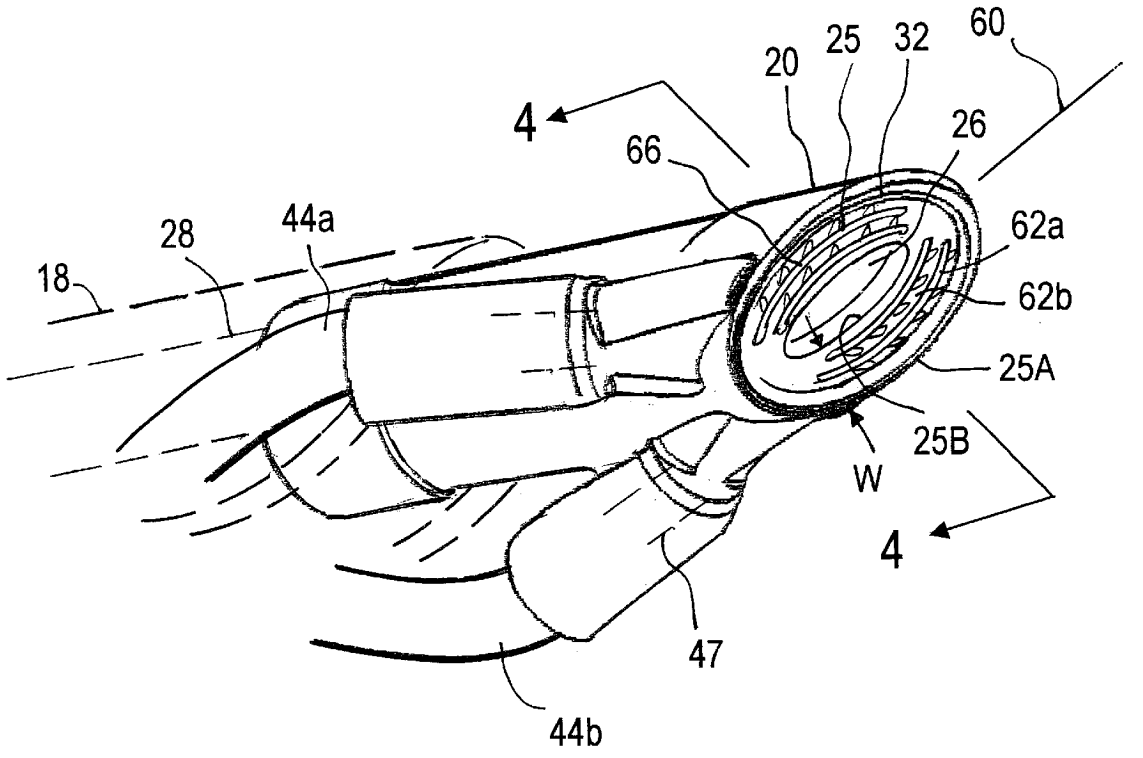


FIG. 3

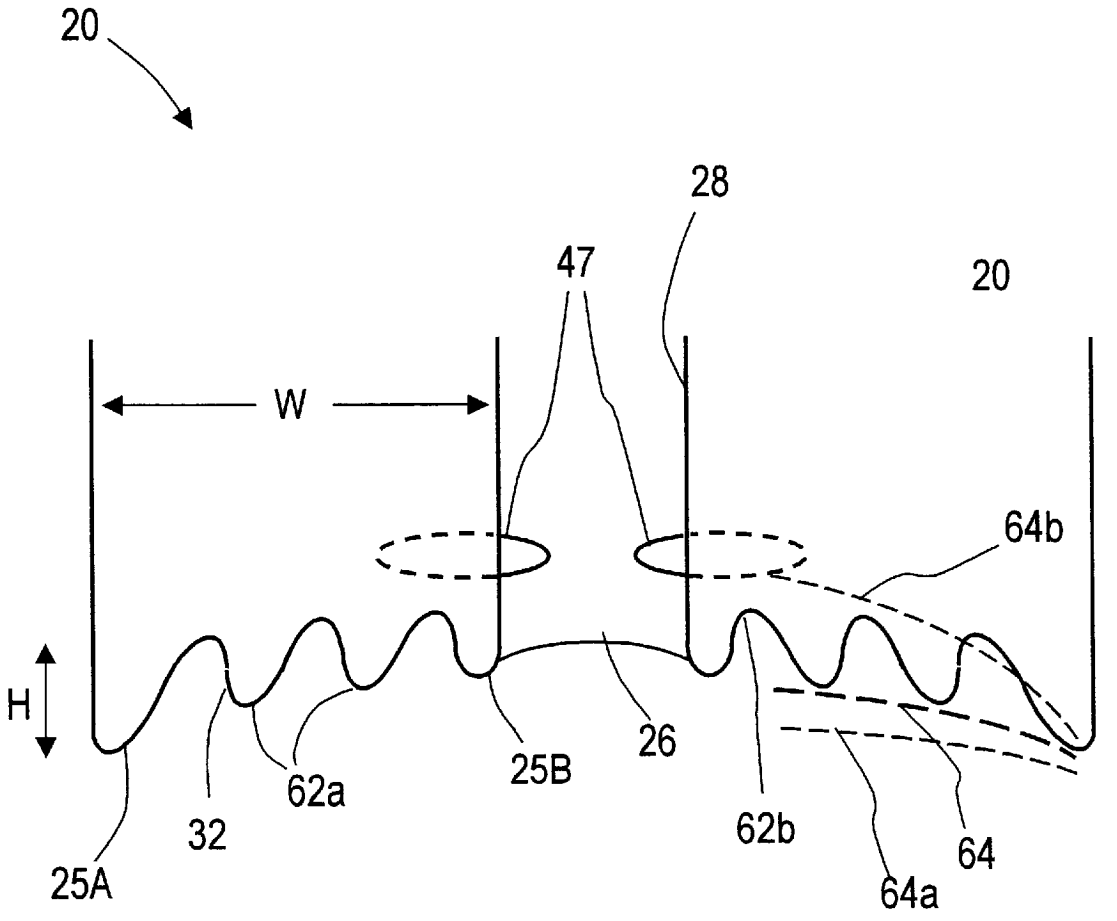


FIG. 4

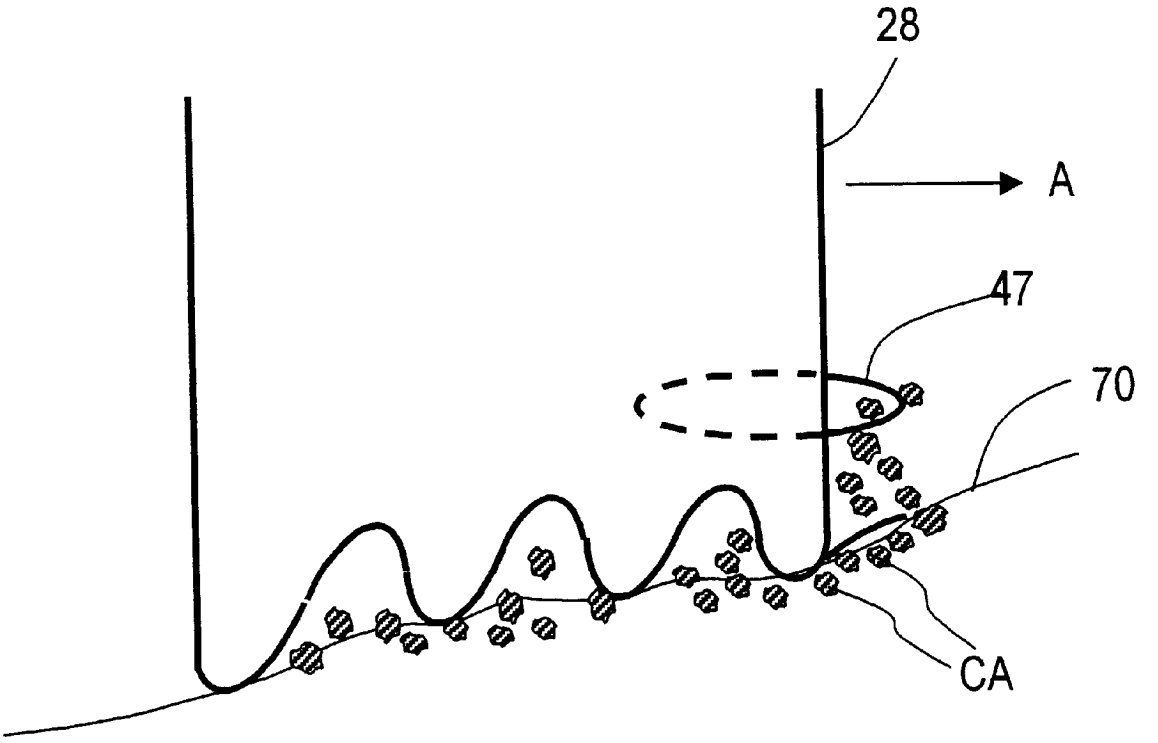


FIG. 5

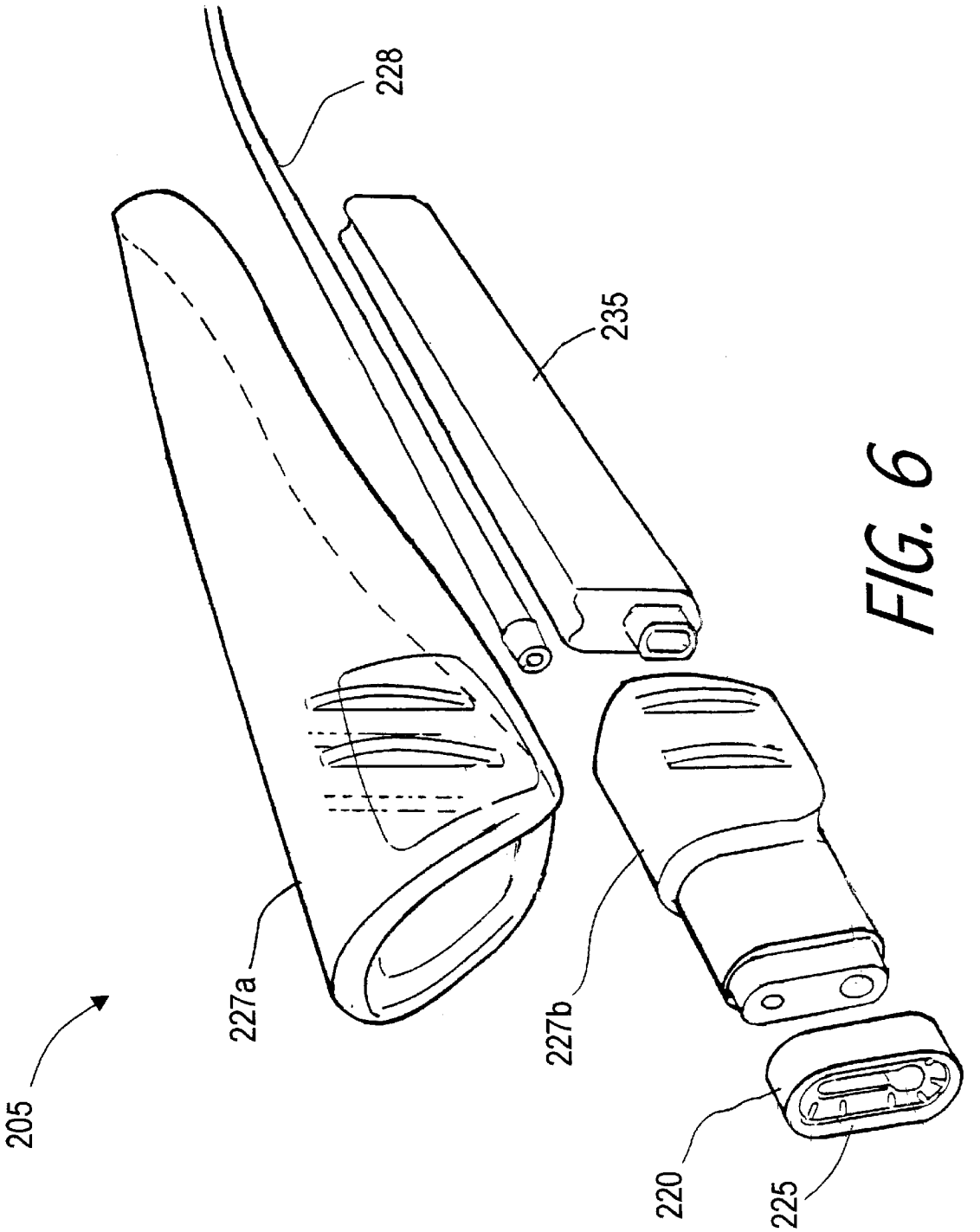


FIG. 6

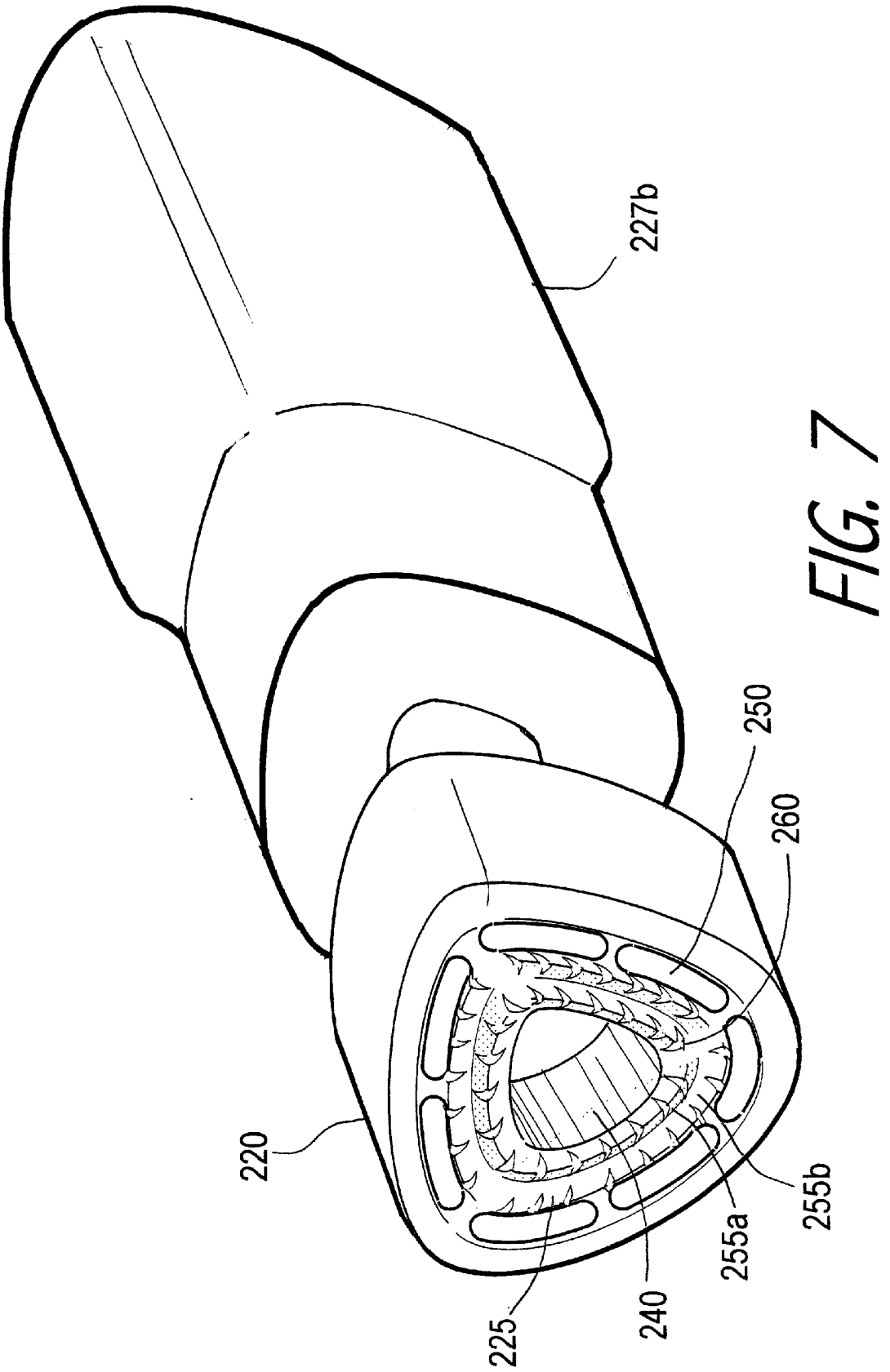


FIG. 7

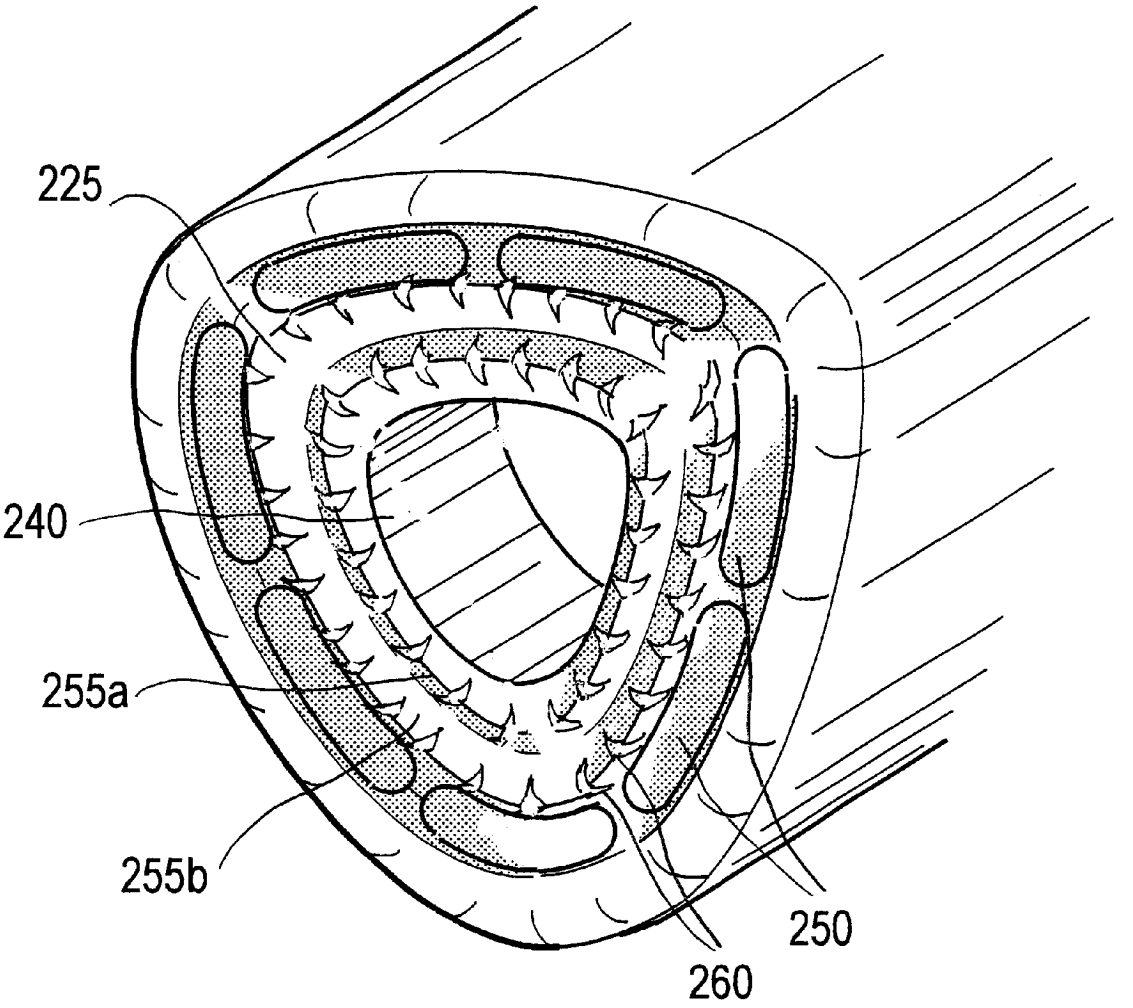


FIG. 8

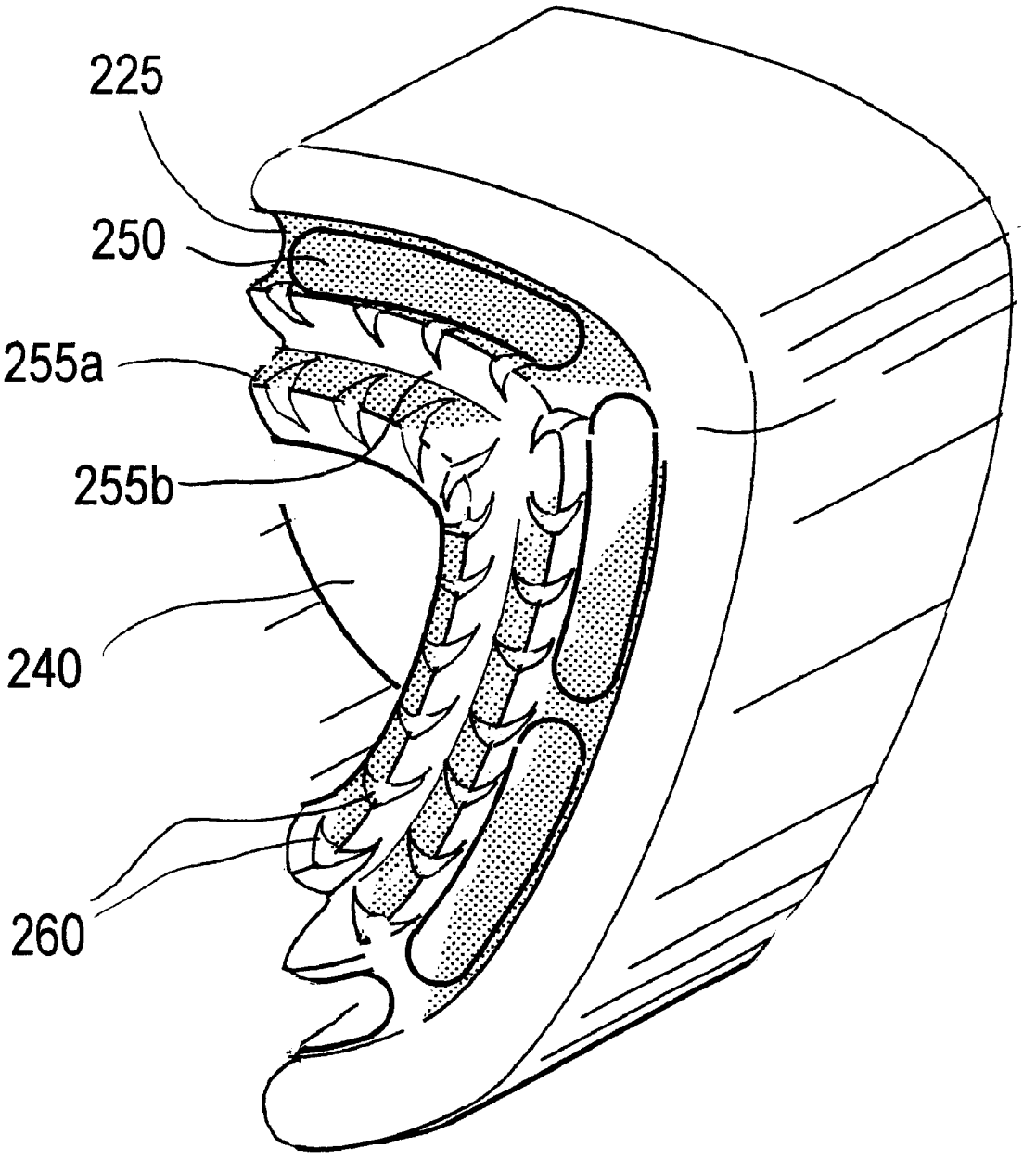


FIG. 9

INSTRUMENTS AND TECHNIQUES FOR CONTROLLED REMOVAL OF EPIDERMAL LAYERS

CROSS-REFERENCE TO RELATED APPLICATIONS

This application claims priority from Provisional U.S. patent application Ser. No. 60/150,782 filed Aug. 26, 1999.

This application is also related to the following U.S. patent applications: Ser. No. 09/294,254 filed Apr. 19, 1999 now U.S. Pat. No. 6,162,232 titled Instruments and Epidermal Layers with Skin Cooling; and Ser. No. 09/271,610 filed Mar. 17, 1999 titled Technique and System for Controlled Chemically-Mediated Removal of Skin Layers. All of the above listed applications are incorporated herein in their entirety by these references.

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates to devices for dermatology and more particularly to a hand-held instrument with a working end that carries (i) a negative pressure aspiration system, (ii) a source for delivery of a sterile fluids to the skin; and (iii) a skin interface surface in the working end that has specially shape structure for abrading surface layers of the patient's epidermis as the working end is moved over the patient's skin while at the same time causing rapid penetration of the fluids into the skin for therapeutic purposes.

2. Description of Background Art

Dermatologists and plastic surgeons have used various methods for removing superficial skin layers to cause the growth of new skin layers (i.e., commonly described as skin resurfacing techniques) since the early 1900's. Early skin resurfacing treatments used an acid such as phenol to etch away surface layers of a patient's skin that contained damage to thereafter be replaced by new skin. (The term damage when referring to a skin disorder is herein defined as any cutaneous defect, e.g., including but not limited to rhytides, hyperpigmentation, acne scars, solar elastosis, other dyschromias, stria distensae, seborrheic dermatitus).

Following the removal of surface skin layers at a particular depth, no matter the method of skin removal, the body's natural wound-healing response begins to regenerate the epidermis and underlying wounded skin layers. The new skin layer will then cytologically and architecturally resemble a younger and more normal skin. The range of resurfacing treatments can be divided generally into three categories based on the depth of the skin removal and wound: (i) superficial exfoliations or peels extending into the epidermis, (ii) medium-depth resurfacing treatments extending into the papillary dermis, and (iii) deep resurfacing treatments that remove tissue to the depth of the reticular dermis (see FIGS. 1A–1B).

Modern techniques for skin layer removal include: CO_2 laser resurfacing which falls into the category of a deep resurfacing treatment; Erbium laser resurfacing which generally is considered a medium-depth treatment; mechanical dermabrasion using high-speed abrasive wheels which results in a medium-depth or deep resurfacing treatment; and chemical peels which may range from a superficial to a deep resurfacing treatment, depending on the treatment parameters. A recent treatment, generally called micro-dermabrasion, has been developed that uses an air-pressure source to deliver abrasive particles directly against a patient's skin at high-velocities to abrade away skin layers.

Such a micnabrasion modality may be likened to sandblasting albeit at velocities that do no cause excess pain and discomfort to the patient. Micro-dermabrasion as currently practiced falls into the category of a superficial resurfacing treatment.

A superficial exfoliation, peel or abrasion removes some or all of the epidermis (see FIGS. 1A–1B) and thus is suited for treating very light rhytides. Such a superficial exfoliation is not effective in treating many forms of damage to skin. A medium-depth resurfacing treatment that extends into the papillary dermis (see FIG. 1B) can treat many types of damage to skin. Deep resurfacing treatments, such as CO_2 laser treatments, that extend well into the reticular dermis (see FIG. 1B) causes the most significant growth of new skin layers but carry the risk of scarring unless carefully controlled.

It is useful to briefly explain the body's mechanism of actually resurfacing skin in response to the removal of a significant depth of dermal layers. Each of the above-listed depths of treatment disrupts the epidermal barrier, or a deeper dermal barrier (papillary or reticular), which initiates varied levels of the body's wound-healing response. A superficial skin layer removal typically causes a limited wound-healing response, including a transient inflammatory response and limited collagen synthesis within the dermis. In a mediumdepth or a deep treatment, the initial inflammatory stage leads to hemostasis through an activated coagulation cascade. Chemotactic factors and fibrin lysis products cause neutrophils and monocytes to appear at the site of the wound The neutrophils sterilize the wound site and the monocytes convert to macrophages and elaborate growth factors which initiate the next phase of the body's wound-healing response involving granular tissue formation. In this phase, fibroblasts generate a new extracellular matrix, particularly in the papillary and reticular dernis, which is sustained by angiogenesis and protected anteriorly by the reforming epithelial layer. The new extracellular matrix is largely composed of collagen fibers (particularly Types I and III) which are laid down in compact parallel arrays (see FIG. 1B). It is largely the collagen fibers that provide the structural integrity of the new skin—and contribute to the appearance of youthful skin.

All of the prevalent types of skin damage (rhytides, solar elastosis effects, hyperpigmentation, acne scars, dyschromias, melasma, stria distensae) manifest common histologic and ultrastructural characteristics, which in particular include disorganized and thinner collagen aggregates, abnormalities in elastic fibers, and abnormal fibroblasts, melanocytes and keratinocytes that disrupt the normal architecture of the dermal layers. It is well recognized that there will be a clinical improvement in the condition and appearance of a patients's skin when a more normal architecture is regenerated by the body's wound-healing response. Of most significance to a clinical improvement is skin is the creation of more dense parallel collagen aggregates with decreased periodicity (spacing between fibrils). The body's wound-healing response is responsible for synthesis of these collagen aggregates. In addition to the body's natural wound healing response, adjunct pharmaceutical treatments that are administered concurrent with, or following, a skin exfoliations can enhance the development of collagen aggregates to provide a more normal dermal architectrre in the skin—the result being a more youthful appearing skin.

The deeper skin resurfacing treatments, such as laser ablation, chemical peels and mechanical dermabrasion have drawbacks. The treatments are best used for treatments of a patient's face and may not be suited for treating other

portions of a patient's body. For example, laser resurfacing of a patient's neck or decolletage may result in post-treatment pigmentation disorders. All the deep resurfacing treatments are expensive, require anesthetics, and must be performed in a clinical setting, Perhaps, the most significant disadvantage to deep resurfacing treatments relates to the post-treatment recovery period. It may require up to several weeks or even months to fully recover and to allow the skin the form a new epidermal layer. During a period ranging from a few weeks to several weeks after a deep resurfacing treatment, the patient typically must wear heavy make-up to cover redness thus making the treatment acceptable only to women.

The superficial treatment offered by microdermabrasion has the advantages of being performed without anesthetics and requiing no extended post-treatment recovery period. However, micro-dermabrasion as currently practices also has several disadvantages. First, a micro-dermabrasion treatment is adapted only for a superficial exfoliation of a patient's epidermis which does not treat many forms of damage to skin. Further, the current micro-dermabrasion devices cause abrasive effects in a focused area of the skin that is very small, for example a few $mm.^2$, since all current devices use a single pin-hole orifice that jets air and abrasives to strike the skin in a highly focused area. Such a focused treatment area is suitable for superficial exfoliations when the working end of the device is passed over the skin in overlapping paths. Further, such focused energy delivery is not well suited for deeper skin removal where repeated passes may be necessary. Still further, current micro-dermabrasion devices are not suited for deeper skin removal due to the pain associated with deep abrasions. Other disadvantages of the current micro-dermabrasion devices relate to the aluminum oxide abrasive particles that are typically used Aluminum oxide can contaminate the working environment and create a health hazard for operators and patients alike. Inhalation of aluminum oxide particles over time can result in serious respiratory disorders.

BRIEF DESCRIPTION OF THE DRAWINGS

FIGS. **1**A–**1**B are sectional illustrations of a patient's skin showing dermal layers.

FIG. **2** is a view of a Type "A" body and working end of the instrument of the invention.

FIG. **3** is an enlarged view of the working end of the instrument of FIG. **2**.

FIG. **4** is a sectional view of working end of FIG. **3**.

FIG. **5** is a view showing the manner of using the working end of the invention of FIGS. **3**–**4** in performing a method of the invention.

FIG. **6** is a view of a Type "B" body, working end and handle in an exploded view.

FIG. **7** is a view of the working end of the instrument of FIG. **6** and a housing.

FIG. **8** is an enlarged view of the skin interface of the working end of FIG. **7**.

FIG. **9** is a sectional view of the skin interface of FIG. **8**.

DETAILED DESCRIPTION OF THE INVENTION

1. Type "A" Skin Resurfacing System. Referring to FIGS. **2**–**3**, an exemplary instrument system **5** is shown for removing superficial skin layers. The instrument system **5** includes: (i) a hand-held body **18** with a working end **20** that defines a skin interface surface portion indicated at **25** in FIGS. **2**–**3**. An opening portion **26** transitions into an interior passageway **28** that extends through the body to communicate with a negative (−) pressure source (or aspiration source) indicated at **30** that operates as vacuum means for aspirating skin debris from a targeted skin surface treatment site TS.

Of particular interest, FIGS. **3**–**4** show views of the working end **20** with the skin interface **25** being configured with a particular irregular or ridged surface structure indicated at **32**. The ridged surface structure **32** further has a particular minimum width dimension W to accommodate from the ridge shape with as many as about **25** ridges on each side of opening **26** depending on the overall dimensions of the working end **20**. More particular aspects of the irregular or ridged surface structure **32** will be described below.

In this preferred embodiment, the working end **20** is of any suitable material, such as a transparent medical grade plastic. The transparency of the working end will assist the operator in localizing treatment in a particular targeted skin treatment area. The overall transverse dimension of the working end **20** of FIGS. **2**–**3** may be from around about 5.0 mm. to about 50.0 mm. with a larger dimensioned end being adapted for treating a larger skin area (e.g., arms, back, legs and decolletage). A typical dimension is from about 5.0 mm. to 15.0 mm. for a skin treatment site area TS around a patient's face.

The invention allows the area (eg., in $mm.^2$) of opening **26** be in any selected shape but preferably is an elongate shape in the center of the working end **25**. The open distal end **26** comprises the distal termination of passageway **28** and the proximal end of the passageway in handle **18** is connected to a flexible aspiration tube **33** that extends to a remote collection reservoir **35** intermediate to the actual aspiration source **30**. The aspiration source **30** thus is adapted to draw the working end **20** and more particularly the skin interface **25** against the skin treatment site TS to perform the method of the invention as will be described below. The aspiration source or negative (−) pressurization source **30** may be any suitable vacuum source known in the art. Between the aspiration source **30** and remote collection reservoir **35** may be a filter **38** subsystem that is known in the art for collecting asprted skin detritus and spent crystalline agents CA that are captued in the open distal end of passageway chamber **28**. The collection reservoir **35** and filter **38** are preferably of inexpensive plastic and other materials that are disposable.

The aspiration source **30** may be provided with an adjustable valve means **40** for adjusting the pressure level setting to any suitable range. The physician will learn from experience how to balance the pressure level to attain the desired level of suction against the patient's skin. A trigger or switch component **42** is provided as a foot-switch (FIG. **2**) but any suitable finger switch in the body **18** also may be used.

The working end **20** also carries means for introducing abrasive crystals into the working end or distalmost end of passageway **28** to allow individual loose crystalline agents CA to thereafter be captured between the skin interface **25** and the patient's skin. In this embodiment, two channels **44***a*–**44***b* are provided together with flexible tubes **46***a*–**46***b* to introduce the loose crystalline agents CA into the working end (see FIGS. **2**–**4**). Each distal portion **47** (collectively) of the channels **44***a*–**44***b* may comprise a small dimension aperture to limit the rate of flow of crystalline agents CA into the working end. The number of such channels (i.e., **44***a*–**44***n*) may range from one to about ten and fall within the scope of the invention. Any singular or plural number of

channels can serve the purpose of slowly introducing crystal into the working end,

Referring to FIGS. **2–3**, the crystalline agent CA delivery source **50** comprises a reservoir **55** that holds a suitable volume of abrasive crystals for a single treatment or a number of treatments. A flexible supply tube **56** extends between a remote the reservoir **55**, and in this embodiment the tube is split to connect to the two channels **44***a*–**44***b*. Preferably, the remote reservoir **55** that carries the crystalline agent CA is unpressurized but carries air intake relief valve **58** such that any slight negative pressure created by the aspiration source **30** when the skin interface is in contact with a patient's skin will draw crystals to the working end. It should be appreciated that reservoir **55** may be built into handle body **18** and fall within the scope of the invention. The crystal delivery source **50** may carry crystals ranging in size from about 1 μm to about 50 μm in maximum cross-sectional dimension, (for example, aluminum oxide crystals). Preferably, the crystals are from about 5 μm to about 30 μm in maximum cross-sectional dimension to allow a very fine abrasion of the epidermis.

It has been found that by a slight negative pressure environment the open end **26** and passageway **28**, the crystalline agent will be caused to dribble into, or be sucked into, the passageway **28** in the working end **20**. Thereafter, the movement of the working end **20** in a sideways movement over the skin causes a portion of the crystalline agent CA volume to be captured temporarily in the irregular or corrugated surface structure of the skin interface **25**. In this process of moving the skin interface **25** over the targeted treatment site TS, it has been found that the sharp edged crystalline agents are rolled over and over while being pressed into the surface of the skin and thereby abrade and remove the skin surface in a controllably gentle manner that is below any threshold of significant pain.

After the spent crystals are rolled over and over by the skin interface when moving in a first lateral direction across the skin, and after the working end is then is reversed in directional movement across the skin, a portion of the spent crystals and abraded skin debris necessarily roll into the central opening portion **26** wherein the negative pressure environment captures and aspirates the abraded materials to the remote collection reservoir **35**.

To facilitate the process described above, the invention is provided with novel aspects that relate to the irregular or ridged surface structure **32** mentioned above. The entire skin interface **25** may be of any suitable plan form (e.g., round, oval, rectangular etc.) and fall within the scope of the invention. More in particular, the interface **25** defines a 1st outer periphery **25**A a 2nd inner periphery **25**B that generally are in apposition to one another and are spaced apart by width W with the inner periphery about the edge of opening **26** (see FIG. **3**).

In a preferred embodiment shown in FIGS. **3–4**, the concept of 1st and 2nd peripheries **25**A and **25**B in apposition thus comprise peripheries that are dual and side-by-side as shown in FIG. **4** and are thus adapted for side-to-side lateral or sideways movement while performing the technique of the invention, for example which is a natural movement of a human hand over a patient's skin. Thus, the direction of the ridges **60** extend generally transverse relative to a line drawn that indicates the direction of movement of the working end **20** in performing the method of the invention. That is, in the exemplary working end of FIG. **4**, the working end is generally optimized for side-to-side or lateral movement. Thus, the ridge alignment is generally transverse to the direction of movement in operations indicated by arrow A. (In a circular working end that is adapted generally for movement is any direction, the direction of the ridges **60** may be generally transverse to any direction of movement by being concentric relative to a central opening **26** (not shown)).

The terms irregular or ridged shape structure **32** as used herein mean that a series of at least one projecting edge portion **62***a* projects distally as a ridge within the skin interface portion **25**. The irregular shape structure **32** further typically carries recessed portions or valley portions **62***b* that are recessed in the proximal direction intermediate to any plurality of projecting edge portions **62***a*. These surface configurations for convenience are herein termed the primary shape structure (or ridge and valley elements). The width of the skin interface **25** containing shape structure **32** may be from about 2.0 mm. to 25.0 mm. or more and preferably is from about 3.0 mm. to 10.0 mm. The number of ridges preferably are from about 1 ridge to 25 ridges on each side of the opening **26**. The height H of any ridge from the apex of the projecting portion **62***a* to the depth of the valley portion **62***b* may be from about 0.25 mm. to about 5.0 mm. and is preferably from about 0.5 mm. to about 2.0 m. It has been found that various ridge height dimensions are optimal depending on the patient's skin type. Further, but optionally, it has been found that secondary shape structure of notches or recessed grooves **66** configured across the primary shape structure of ridge and valley elements may help introduce loose crystals to regions of the skin interface **25** in contact with the skin which is desirable. Such secondary grooves **66** are shown in FIG. **4** and are preferably somewhat in alignment with an axis of channels **44***a***14 44***b* that introduce crystals into the working end **20** thus allowing the crystals to be suctioned into the valleys **62***b* of the primary shape structure.

While the series of primary ridge and valley elements together the secondary grooves seems to be optimal for the method described below, it should be appreciated that the method also may be performed with a skin interface that has (i) only primary ridge and valley elements; (ii) or only a particular surface roughness that is appropriate for partially capturing loose crystals as will be described below—as long as the skin interface has a minimum width of about 3.0 mm. which was described as a preferred width dimension previously.

FIG. **4** further shows that at least some of the crests or apexes of some of the ridge portions **62***a* together with the outermost periphery of the skin interface **25** define an overall tissue-receiving shape **64** that may range from flat to concave and is shown in a preferred concave configuration. The alternative shapes **64***a*–**64***b* are intended to indicate an approximate range of shapes that are suitable. The apexes of ridges **62***a* need not all be at the same height to define shape **64**. The purpose of the concave shape is to cause the outer periphery of the working end to be in firm contact with the tissue surface while the negative pressure from aspiration source **30** draws the skin into firm contact with tissue interface **25**.

2. Practice of the Method of the Invention. Now tuning to FIG. **5**, a sectional view of working end **20** shows the technique of the present invention in exfoliating or removing skin surface layers. FIG. **5** shows the working end **20** after actuation of the negative (−) pressure source **30** with the skin surface **70** initially being drawn into the concave shape **64**. The operating negative pressures may be in any suitable range that is determined by investigation. It has been found by experimentation that optimal pressure levels vary greatly

depending on (i) the type of skin targeted for treatment, (ii) the dimensions across the working end, and (iii) the dimensions of opening **26**.

Next, the operator moves the skin interface **25** across a treatment site TS which is a path on the patient's skin while still actuating moves the trigger **42** thereby maintaining the negative pressure environment in the passageway **26**. The negative pressure environment within the working end causes crystalline particles and entrained in air to be drawn into passageway **28** proximate to the skin surface and into the shape structure **32** of the skin interface **25**. The sideways or lateral movement of the skin interface **25** captures a portion of the crystals between the interface and the skin surface, in part by over-rotting them. The continued rolling of the sharp-edged crystals trapped between the instrument and the skin surface **70** causes an abrasion and removal of the skin surface in a controllable manner.

As working end is moved in a reverse direction, the negative pressure environment in the passageway **28** captures and aspirates the spent crystals and skin debris to the remote collection reservoir **35**. At the end of a particular lateral movement of the working end, the operator may release the trigger **42** which terminates the crystal agent delivery and further allows the operator to easily lift the working end from the patient's skin. The treated path can be easily seen and the operator then can exfoliate another slightly overlapping or adjacent path by repeating the above steps until surface removal is completed over the targeted treatment area.

3. Type "B" Skin Resurfacing System. Referring to FIGS. **6–9**, another exemplary instrument system and treatment device **205** is shown for removing superficial skin layers. This system differs greatly from the Type "A" embodiment in the mechanism of action that abrades the skin since the Type "B" system uses a fluid media plus an abrading structure on the skin interface. Still several features of the Type "B" embodiment are similar to the Type "A" embodiment and the two modalities of treatment may be used to complement one another.

FIG. **6** shows that a hand-held instrument **208** has a removable working end **220** that defines a skin interface surface portion indicated at **225**. Handle portion **227***a* mates with housing **227***b*. A flexible tube **228** extends to a vacuum source **230**. A fluid reservoir **235** carrying a fluid skin treatment media is housed in the handle although it could also be a remote reservoir.

Referring now to FIGS. **7–9**, a first aperture arrangement consisting of at least one port or opening portion **240** of skin interface **225** that communicates with an interior passageway **242** that extends through housing **227***b* to hose **228** and the vacuum or negative (−) pressure source.

FIGS. **7–9** further show a second aperture arrangement in the skin interface consisting of at least one port or openings **250** that extend around an outer periphery of the skin interface **225**. These opening(s) of the second aperture arrangement are in fluid communication with the reservoir **235** and the treatment media therein. The skin interface has a series of primary ridge elements **255***a* and valley elements **255***b* together the secondary notches or grooves **260** as defined above with similar dimensional parameters. This embodiment differs however in that the apexes of ridge elements **255***a* are substantially a sharp edge as are the edged of the notches **260**. Thus, these primary surface elements **255***a* and secondary surface elements thereby define teeth therebetween that seem well suited to abrading skin layers particularly after being hydrated by the fluid source of the system. Experimentation has shown that the vacuum source and fluid source may be reversed between the first and second aperture arrangements **240** and **250** with the method of skin removal still working well. The vacuum system aspirates away skin debris and spent fluids as described previously. Of particular interest, the method of the invention appears to work well because the suction on the skin treatment site very quickly hydrated, or puffs up, the skin which in turn make the surface layer susceptible to painless abrasion. The ability of the system to rapidly deliver fluids to subsurface tissues allows the use of any pharmacological agent known in the art for enhancing skin rejuvenation as a part of the skin treatment. The system can use sterile water or saline solution for a treatment to remove dermal tissue with the abrasive surface of the treatment device. The system can also use a fluid carrying a chemical agent of a suitable concentration be selected from a group of acids including TCA (trichloroacetic acid), a glycolic acid including an alphahydroxy acid (AHA), a lactic acid, a citric acid, or phenol as disclosed in co-pending U.S. patent application Ser. No. 09/524,731 filed Mar. 14, 2000 which is incorporated herein by this reference.

Specific features of the invention may be shown in some figures and not in others, and this is for convenience only and any feature may be combined with another in accordance with the invention. While the principles of the invention have been made clear in the exemplary embodiments, it will be obvious to those skilled in the art that modifications of the structure, arrangement, proportions, elements, and materials may be utilized in the practice of the invention, and otherwise, which are particularly adapted to specific environments and operative requirements without departing from the principles of the invention. The appended claims are intended to cover and embrace any and all such modifications, with the limits only of the true purview, spirit and scope of the invention.

What is claimed is:

1. A system for treating the skin surface of a patient, comprising:

(a) an instrument body with a distal working end that defines a skin interface portion for contacting the skin;

(b) a first aperture arrangement in said skin interface consisting of at least one port in communimcation with a treatment media source;

(c) a second aperture arrangement in said skin interface consisting of at least one port in communication with a vacuum source for removing treatment media and removed tissue from the skin interface; and

(d) wherein the skin interface comprises an abrading structure with substantially sharp edges for abrading tissue.

2. The system of claim **1** wherein said skin interface defines a plurality of projecting ridges having a minimum width of about 2.0 mm.

3. The system of claim **2** wherein said skin interface and plurality of projecting ridges extends at least partially around the first aperture arrangement.

4. The system of claim **1** wherein said skin interface portion has shape irregularities comprising distally projecting apices and recessed portions therebetween.

5. The system of claim **4** wherein said skin interface portion has a primary surface structure of distally projecting apices and recessed portions therebetween together with a secondary surface structure of recessed grooves extending across the primary surface structure.

6. The system of claim **1** wherein said treatment media source carries a fluid.

7. The system of claim 6 wherein the fluid is sterile water or saline solution.

8. The system of claim 6 wherein the fluid carries an agent selected from the class comprising TCA (trichloroacetic acid), glycolic acid, alphahydroxy acid (AHA), lactic acid, and citric acid.

9. The system of claim 1 wherein said treatment media source carries a crystalline agent.

10. A method for treating the skin surface of a patient, comprising:

positioning a treatment device against a patient's skin creating a treatment region at a skin treatment site, the treatment device comprising at least one media entrance port;

directing at least one flowable treatment medium through said at least one entrance port;

wherein the treatment medium is sterile water or a saline solution;

translating the treatment device over the skin treatment site whereby the combination of an abrasive structure carried by the treatment device and the flowable treatment medium removes dermal tissue; and

aspirating dermal treatment media and any removed dermal tissue from the treatment region.

11. The method of claim 10 wherein the treatment media further comprises an agent selected from the class comprising TCA (trichloroacetic acid), glycolic acid, alphahydroxy acid (AHA), lactic acid, and citric acid.

12. A method for treating the skin surface of a patient, comprising:

positioning a treatment device against a patient's skin creating a treatment region at a skin treatment site, the treatment device comprising at least one media entrance port;

directing at least one flowable treatment medium through said at least one entrance port;

wherein the treatment medium comprises a crystalline agent;

translating the treatment device over the skin treatment site whereby surface irregularities of the treatment device partially capture the crystalline agents to remove dermal tissue; and

aspirating dermal treatment media and any removed dermal tissue from the treatment region.

13. The method of claim 12 wherein said crystalline agents range in size from about 1 μm to about 50 μm in crosstional dimension.

14. The method of claim 12 wherein said surface irregularities comprise a surface roughness that cooperates with crystalline agents ranging in size from about 1 μm to about 50 μm in cross-sectional dimension.

15. A system for treating the skin surface of a patient, comprising:

an instrument body with a distal working surface that carries an abrading structure for engaging and abrading the skin;

an interior channel in the instrument body extending between a first end and a distal open termination in the working surface;

a vacuum source coupled to said first end of the interior channel for suctioning the skin against the working surface and for removing abraded skin;

wherein the abrading structure defines a plurality of sharp apices and is carried about a plurality of grooves in the working surface; and

at least one media inflow port in the working surface for delivering a flowable media to the skin during treatment.

16. A system for treating the skin surface of a patient, comprising:

an instrument body with a distal working surface that carries an abrading structure for engaging and abrading the skin;

an interior channel in the instrument body extending between a first end and a distal open termination in the working surface;

a vacuum source coupled to said first end of the interior channel for suctioning the skin against the working surface and for removing abraded skin;

wherein the abrading structure defines a plurality of sharp apices and is carried about a plurality of grooves in the working surface; and

at least one media inflow port in the working surface that communicates with a fluid media source.

17. A system for treating the skin surface of a patient, comprising:

an instrument body with a distal working surface that carries an abrading structure for engaging and abrading the skin;

an interior channel in the instrument body extending between a first end and a distal open termination in the working surface;

a vacuum source coupled to said first end of the interior channel for suctioning the skin against the working surface and for removing abraded skin;

wherein the abrading structure defines a plurality of sharp apices and is carried about a plurality of grooves in the working surface; and

at least one media inflow port in the working surface that communicates with a fluid media source wherein the fluid media source carries a fluid agent selected from the class of skin rejuvenation fluid agents carrying a pharmacologically-active agent or an acid for etching the skin surface.

* * * * *

EXHIBIT 2

US007678120B2

(12) **United States Patent**
Shadduck

(10) **Patent No.: US 7,678,120 B2**
(45) **Date of Patent: *Mar. 16, 2010**

(54) **INSTRUMENTS AND TECHNIQUES FOR CONTROLLED REMOVAL OF EPIDERMAL LAYERS**

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(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 104 days.

This patent is subject to a terminal disclaimer.

(21) Appl. No.: **11/417,396**

(22) Filed: **May 3, 2006**

(65) **Prior Publication Data**

US 2006/0200172 A1 Sep. 7, 2006

Related U.S. Application Data

(63) Continuation of application No. 10/699,747, filed on Nov. 3, 2003, which is a continuation of application No. 09/648,025, filed on Aug. 25, 2000, now Pat. No. 6,641,591.

(60) Provisional application No. 60/150,782, filed on Aug. 26, 1999.

(51) **Int. Cl.**
A61B 17/50 (2006.01)
A61M 35/00 (2006.01)

(52) **U.S. Cl.** **606/131**; 606/132; 604/289

(58) **Field of Classification Search** 606/131, 606/132, 133; 604/289, 313, 315
See application file for complete search history.

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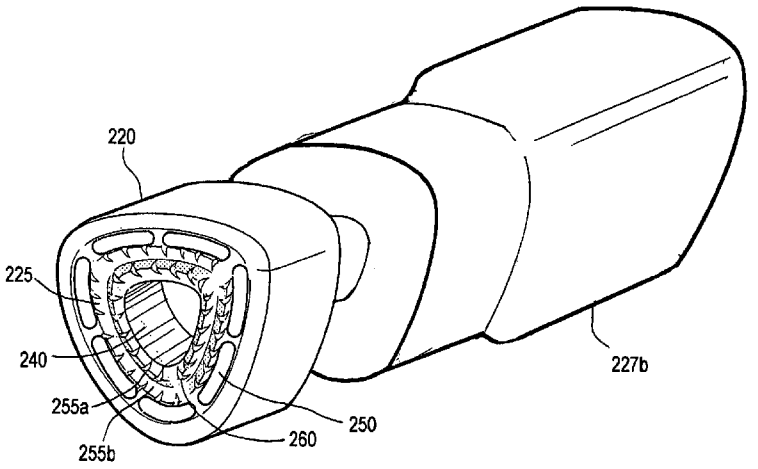
(74) *Attorney, Agent, or Firm*—Knobbe Martens Olson & Bear, LLP

(57) **ABSTRACT**

An instrument and technique for the removal of epidermal layers in a controlled manner utilizing a hand-held instrument with a working end that (i) a vacuum aspiration system, (ii) a source for delivery of a sterile fluids or pharmacological agents to the skin; and (iii) a skin interface surface in the working end that has specially shape structure for abrading surface layers of the patient's epidermis as the working end is moved over the patient's skin while at the same time causing rapid penetration of the fluids into the skin for therapeutic purposes. Movement of the working end across the skin causes abrasion of the surface layers in a path over the patient's skin. The method of the invention may be used in a periodic treatment for the removal of superficial skin layers that enhances the synthesis of dermal collagen aggregates by inducing the body's natural wound healing response. The method of the invention creates more normal dermal architectures in skin with limited depths of skin removal by the series of superficial treatments that may be comparable to the extent of neocollagenesis caused by a deep skin removal treatment (e.g., CO^2 laser skin removal).

9 Claims, 9 Drawing Sheets



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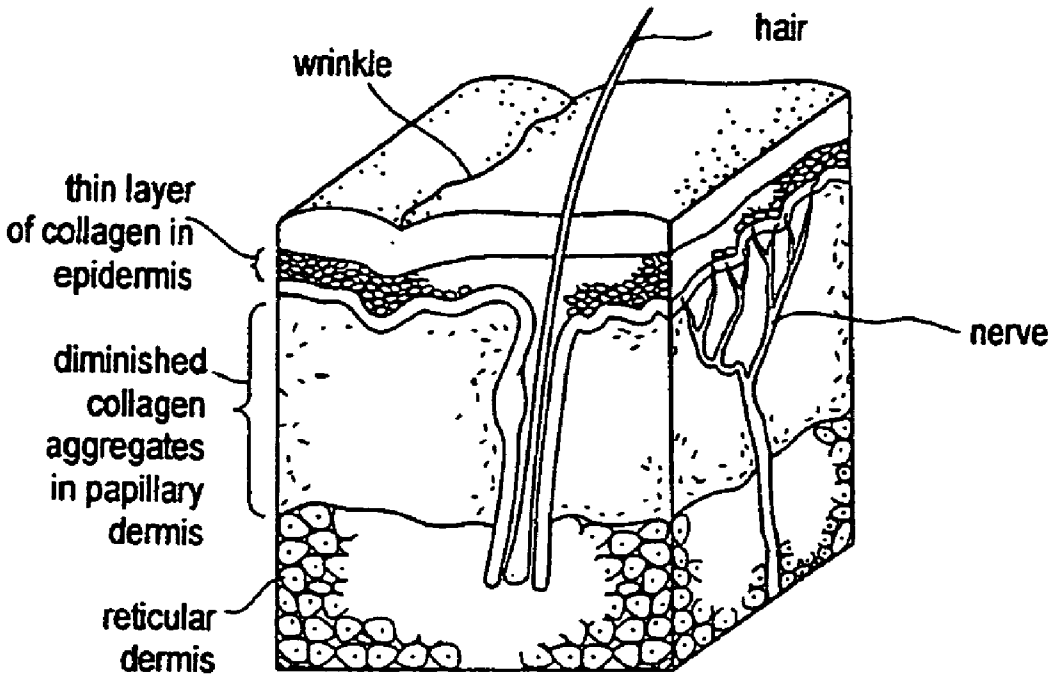
hair
wrinkle
thin layer of collagen in epidermis
diminished collagen aggregates in papillary dermis
reticular dermis
nerve

FIG. 1A

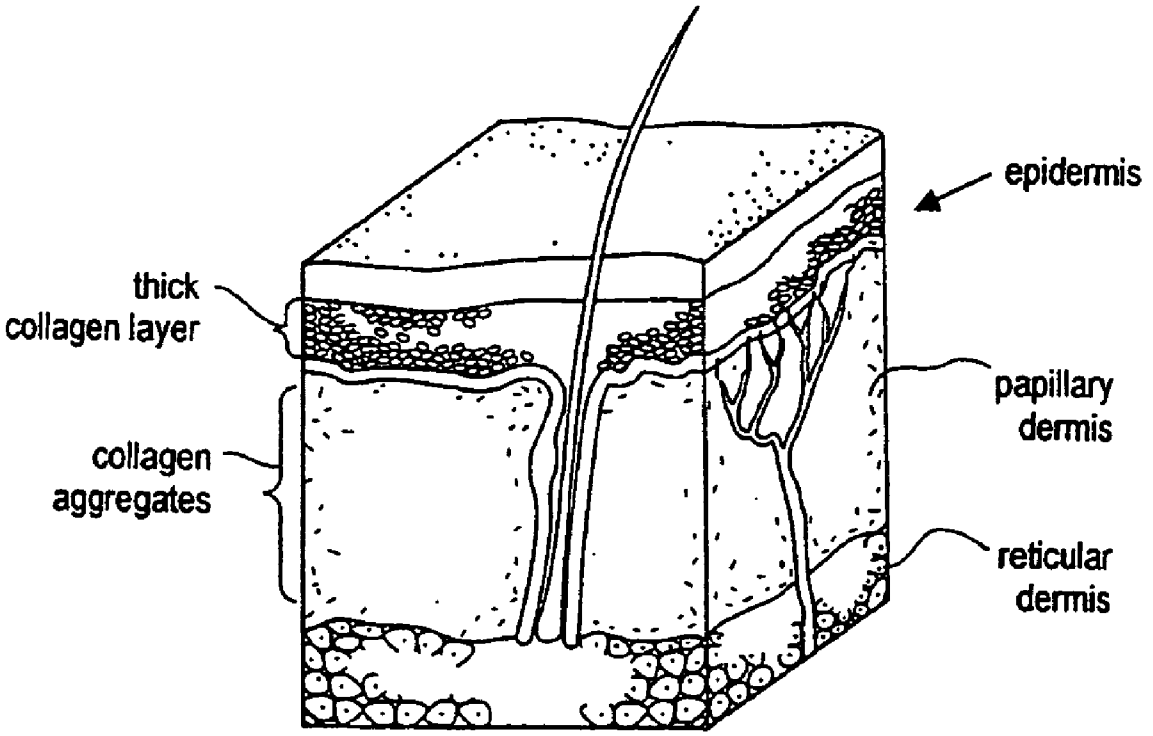
epidermis
thick collagen layer
collagen aggregates
papillary dermis
reticular dermis

FIG. 1B

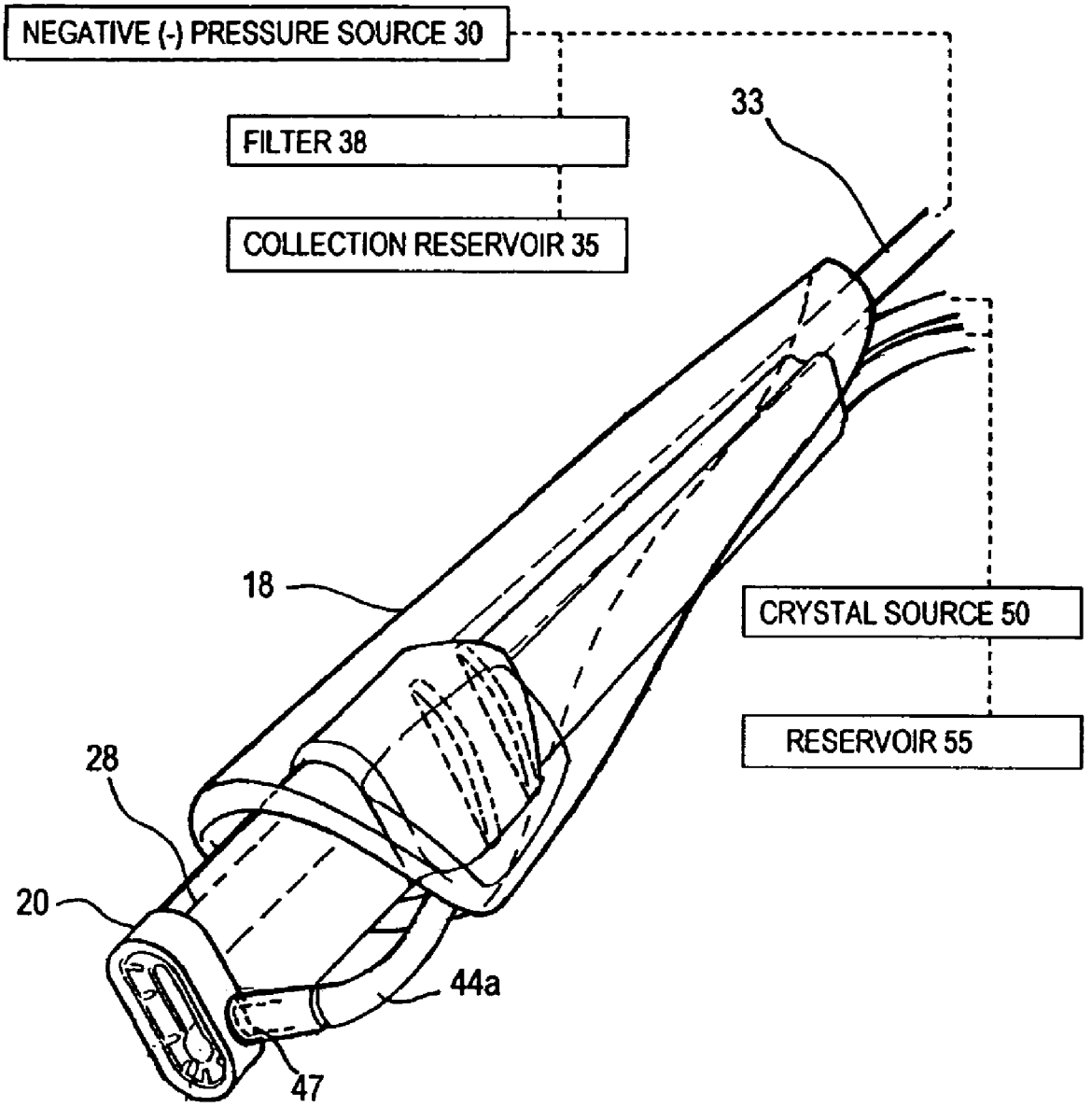
NEGATIVE (-) PRESSURE SOURCE 30
FILTER 38
COLLECTION RESERVOIR 35
33
18
CRYSTAL SOURCE 50
RESERVOIR 55
28
20
44a
47

FIG. 2

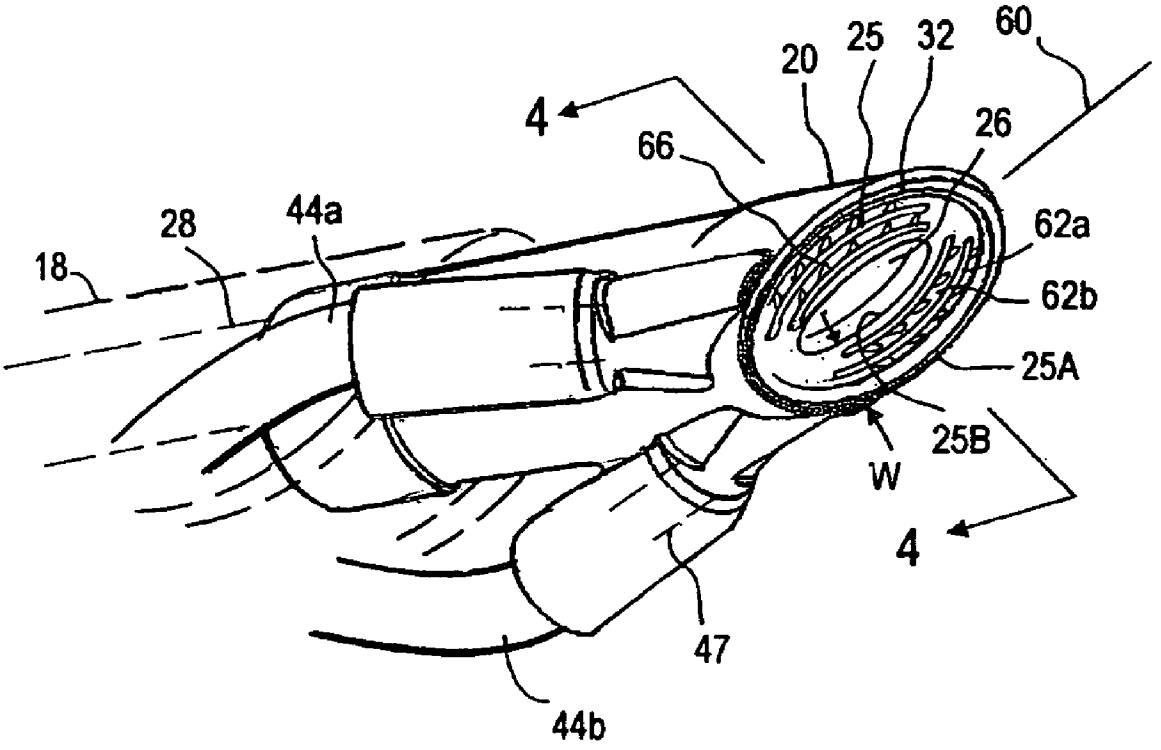

FIG. 3

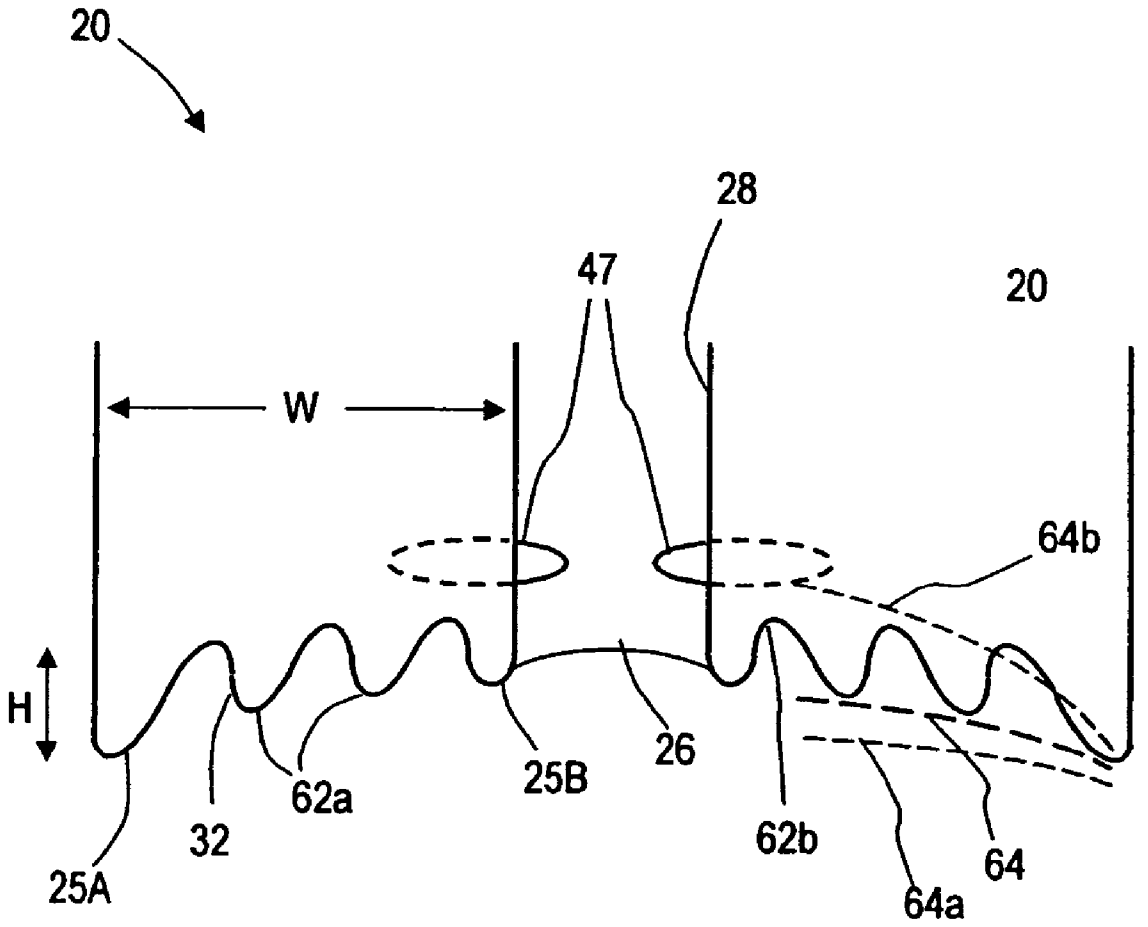

FIG. 4

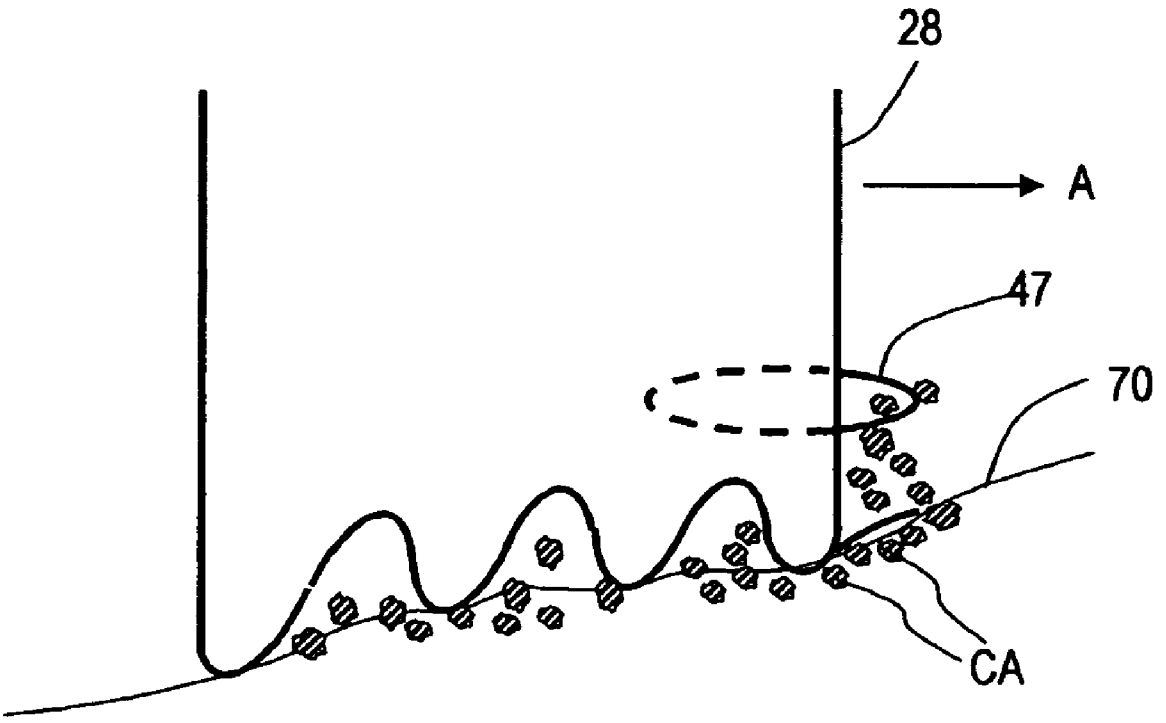

FIG. 5

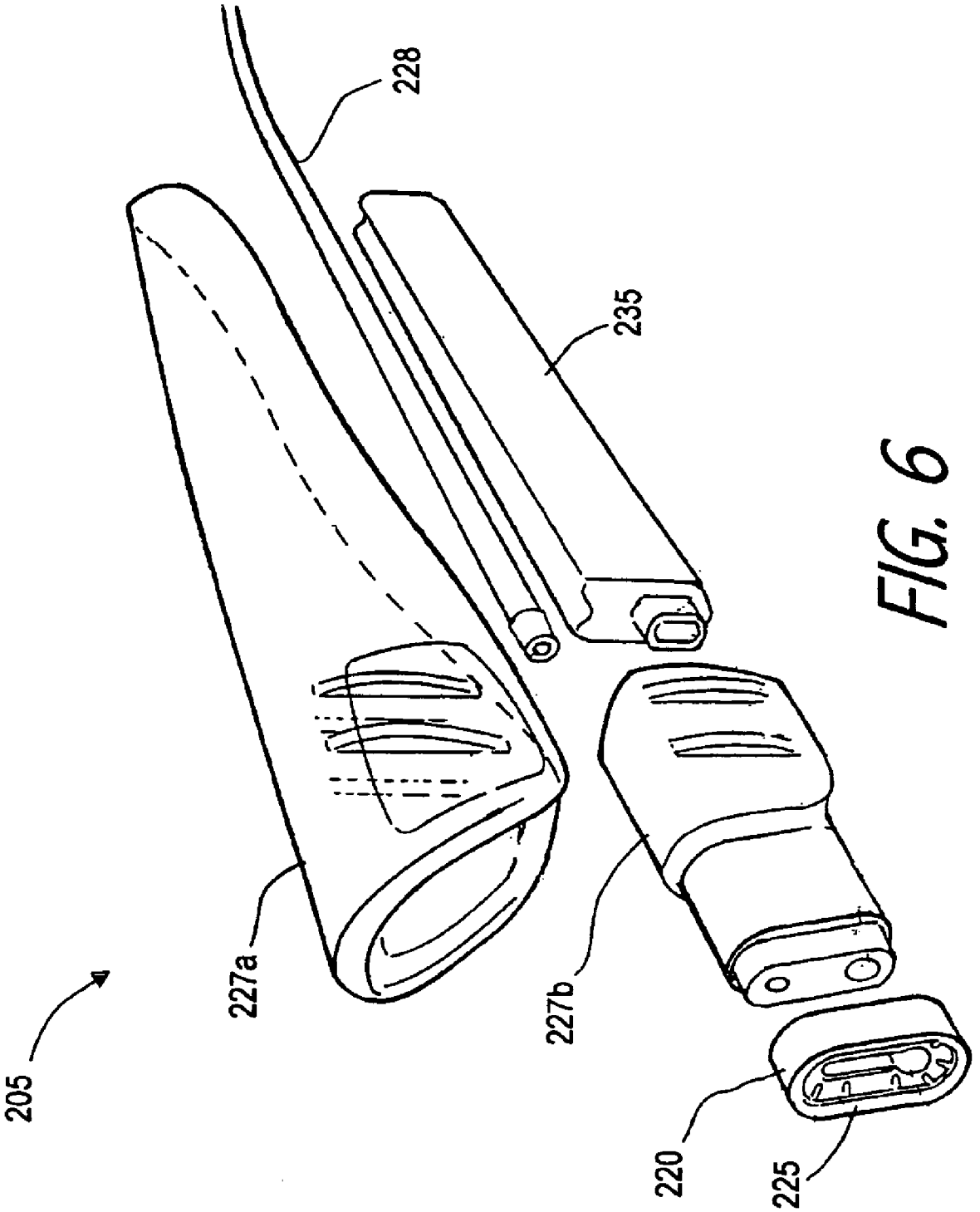

FIG. 6

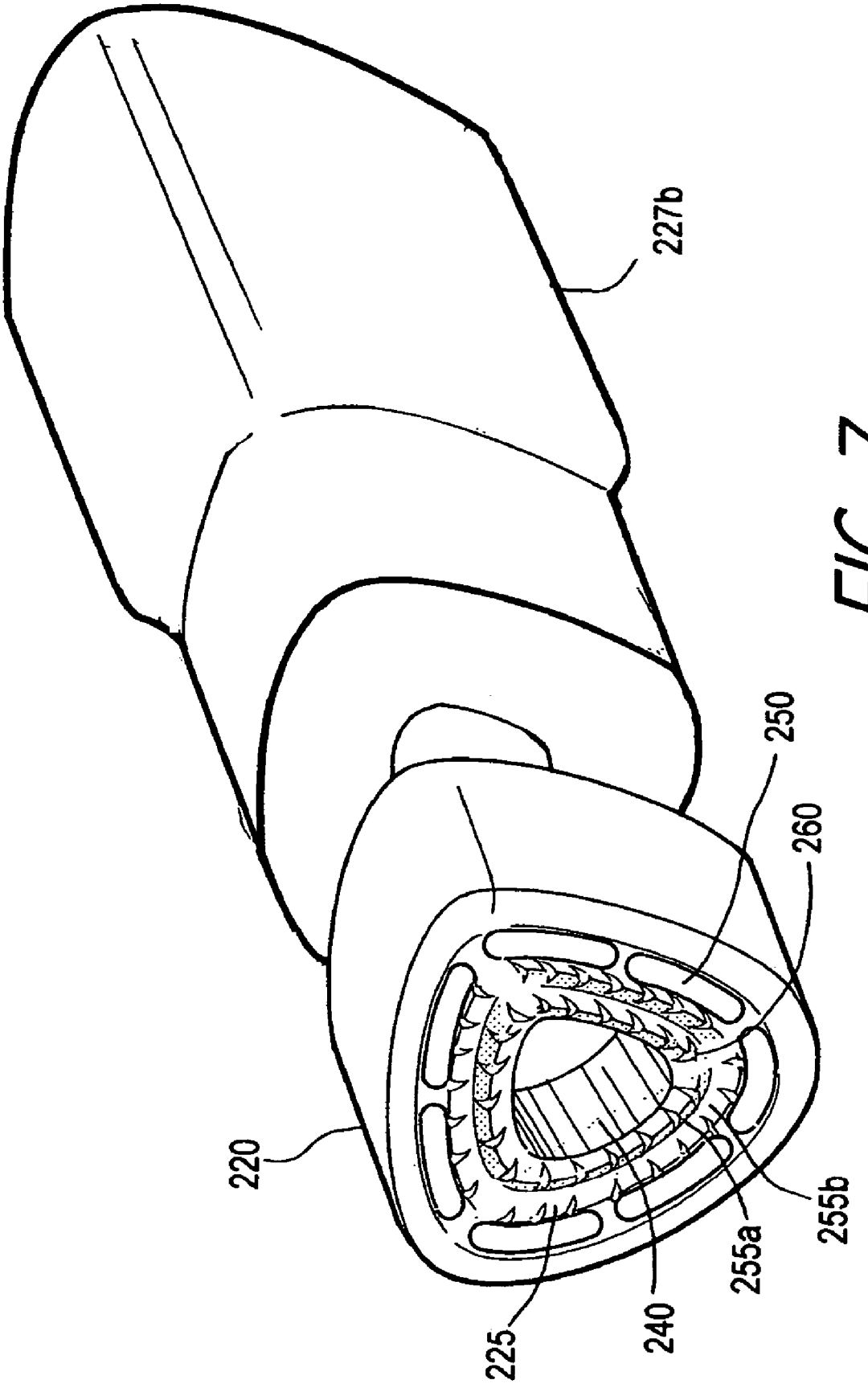

FIG. 7

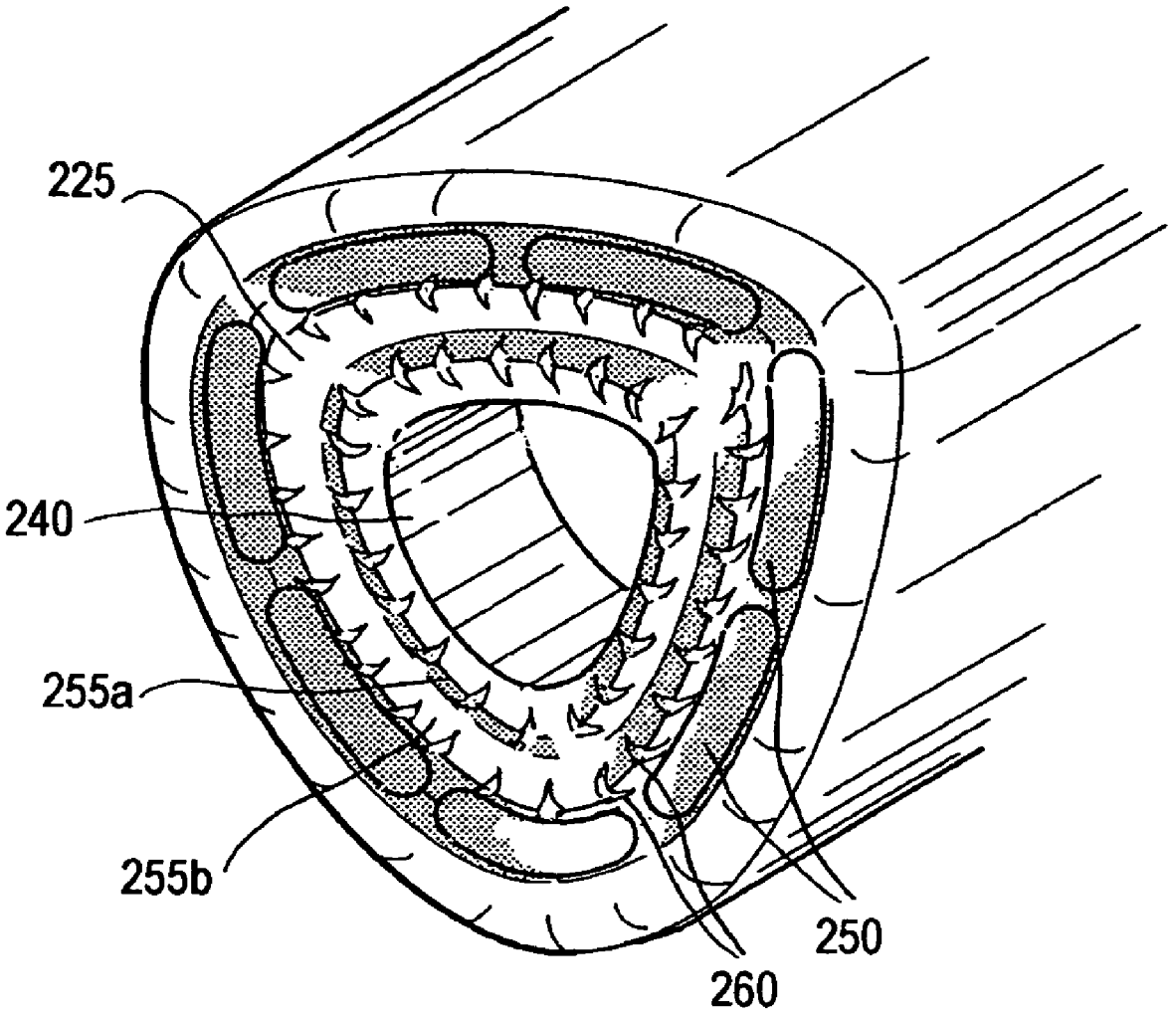

FIG. 8

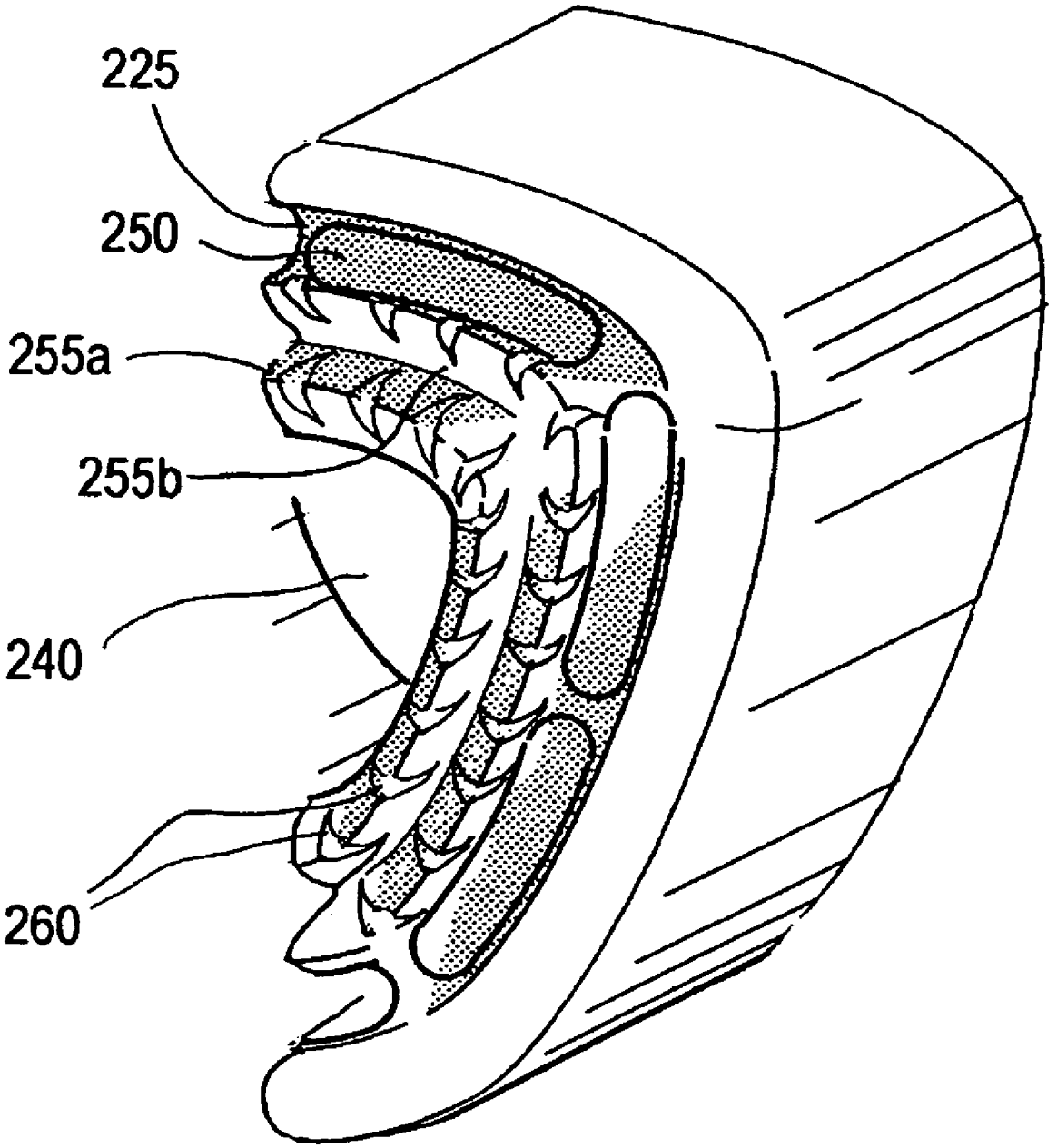

FIG. 9

INSTRUMENTS AND TECHNIQUES FOR CONTROLLED REMOVAL OF EPIDERMAL LAYERS

PRIORITY INFORMATION

This application is a continuation of U.S. patent application Ser. No. 10/699,747, filed Nov. 3, 2003, which is a continuation of U.S. patent application Ser. No. 09/648,025 filed Aug. 25, 2000, now U.S. Pat. No. 6,641,591, which claims the priority benefit under 35 U.S.C. §119(e) of Provisional U.S. Patent Application Ser. No. 60/150,782, filed Aug. 26, 1999, the entire contents of these applications being hereby incorporated by reference herein.

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates to devices for dermatology and more particularly to a hand-held instrument with a working end that carries (i) a negative pressure aspiration system, (ii) a source for delivery of a sterile fluids to the skin; and (iii) a skin interface surface in the working end that has specially shape structure for abrading surface layers of the patient's epidermis as the working end is moved over the patient's skin while at the same time causing rapid penetration of the fluids into the skin for therapeutic purposes.

2. Description of the Related Art

Dermatologists and plastic surgeons have used various methods for removing superficial skin layers to cause the growth of new skin layers (i.e., commonly described as skin resurfacing techniques) since the early 1900's. Early skin resurfacing treatments used an acid such as phenol to etch away surface layers of a patient's skin that contained damage to thereafter be replaced by new skin. (The term damage when referring to a skin disorder is herein defined as any cutaneous defect, e.g., including but not limited to rhytides, hyperpigmentation, acne scars, solar elastosis, other dyschromias, stria distensae, seborrheic dermatitus).

Following the removal of surface skin layers at a particular depth, no matter the method of skin removal, the body's natural wound-healing response begins to regenerate the epidermis and underlying wounded skin layers. The new skin layer will then cytologically and architecturally resemble a younger and more normal skin. The range of resurfacing treatments can be divided generally into three categories based on the depth of the skin removal and wound: (i) superficial exfoliations or peels extending into the epidermis, (ii) medium-depth resurfacing treatments extending into the papillary dermis, and (iii) deep resurfacing treatments that remove tissue to the depth of the reticular dermis (see FIGS. **1**A-**1**B).

Modem techniques for skin layer removal include: CO.sub.2 laser resurfacing which falls into the category of a deep resurfacing treatment; Erbium laser resurfacing which generally is considered a medium-depth treatment; mechanical dermabrasion using high-speed abrasive wheels which results in a medium-depth or deep resurfacing treatment; and chemical peels which may range from a superficial to a deep resurfacing treatment, depending on the treatment parameters. A recent treatment, generally called micro-dermabrasion, has been developed that uses an air-pressure source to deliver abrasive particles directly against a patient's skin at high-velocities to abrade away skin layers. Such a micro-dermabrasion modality may be likened to sandblasting albeit at velocities that do no cause excess pain and discomfort to the patient. Micro-dermabrasion as currently practiced falls into the category of a superficial resurfacing treatment.

A superficial exfoliation, peel or abrasion removes some or all of the epidermis (see FIGS. **1**A-**1**B) and thus is suited for treating very light rhytides. Such a superficial exfoliation is not effective in treating many forms of damage to skin. A medium-depth resurfacing treatment that extends into the papillary dermis (see FIG. **1**B) can treat many types of damage to skin. Deep resurfacing treatments, such as CO.sub.2 laser treatments, that extend well into the reticular dermis (see FIG. **1**B) causes the most significant growth of new skin layers but carry the risk of scarring unless carefully controlled.

It is useful to briefly explain the body's mechanism of actually resurfacing skin in response to the removal of a significant depth of dermal layers. Each of the above-listed depths of treatment disrupts the epidermal barrier, or a deeper dermal barrier (papillary or reticular), which initiates varied levels of the body's wound-healing response. A superficial skin layer removal typically causes a limited wound-healing response, including a transient inflammatory response and limited collagen synthesis within the dermis. In a medium-depth or a deep treatment, the initial inflammatory stage leads to hemostasis through an activated coagulation cascade. Chemotactic factors and fibrin lysis products cause neutrophils and monocytes to appear at the site of the wound. The neutrophils sterilize the wound site and the monocytes convert to macrophages and elaborate growth factors which initiate the next phase of the body's wound-healing response involving granular tissue formation. In this phase, fibroblasts generate a new extracellular matrix, particularly in the papillary and reticuilar dermis, which is sustained by angiogenesis and protected anteriorly by the reforming epithelial layer. The new extracellular matrix is largely composed of collagen fibers (particularly Types I and III) which are laid down in compact parallel arrays (see FIG. **1**B). It is largely the collagen fibers that provide the structural integrity of the new skin—and contribute to the appearance of youthful skin.

All of the prevalent types of skin damage (rhytides, solar elastosis effects, hyperpigmentation, acne scars, dyschromias, melasma, stria distensae) manifest common histologic and ultrastructural characteristics, which in particular include disorganized and thinner collagen aggregates, abnormalities in elastic fibers, and abnormal fibroblasts, melanocytes and keratinocytes that disrupt the normal architecture of the dermal layers. It is well recognized that there will be a clinical improvement in the condition and appearance of a patient's skin when a more normal architecture is regenerated by the body's wound-healing response. Of most significance to a clinical improvement is skin is the creation of more dense parallel collagen aggregates with decreased periodicity (spacing between fibrils). The body's wound-healing response is responsible for synthesis of these collagen aggregates. In addition to the body's natural wound healing response, adjunct pharmaceutical treatments that are administered concurrent with, or following, a skin exfoliations can enhance the development of collagen aggregates to provide a more normal dermal architecture in the skin—the result being a more youthful appearing skin.

The deeper skin resurfacing treatments, such as laser ablation, chemical peels and mechanical dermabrasion have drawbacks. The treatments are best used for treatments of a patient's face and may not be suited for treating other portions of a patient's body. For example, laser resurfacing of a patient's neck or decolletage may result in post-treatment pigmentation disorders. All the deep resurfacing treatments are expensive, require anesthetics, and must be performed in

a clinical setting. Perhaps, the most significant disadvantage to deep resurfacing treatments relates to the post-treatment recovery period. It may require up to several weeks or even months to fully recover and to allow the skin the form a new epidermal layer. During a period ranging from a few weeks to several weeks after a deep resurfacing treatment, the patient typically must wear heavy make-up to cover redness thus making the treatment acceptable only to women.

The superficial treatment offered by micro-dermabrasion has the advantages of being performed without anesthetics and requiring no extended post-treatment recovery period. However, micro-dermabrasion as currently practices also has several disadvantages. First, a micro-dermabrasion treatment is adapted only for a superficial exfoliation of a patient's epidermis which does not treat many forms of damage to skin. Further, the current micro-dermabrasion devices cause abrasive effects in a focused area of the skin that is very small, for example a few mm.sup.2, since all current devices use a single pin-hole orifice that jets air and abrasives to strike the skin in a highly focused area. Such a focused treatment area is suitable for superficial exfoliations when the working end of the device is passed over the skin in overlapping paths. Further, such focused energy delivery is not well suited for deeper skin removal where repeated passes may be necessary. Still further, current micro-dermabrasion devices are not suited for deeper skin removal due to the pain associated with deep abrasions. Other disadvantages of the current micro-dermabrasion devices relate to the aluminum oxide abrasive particles that are typically used. Aluminum oxide can contaminate the working environment and create a health hazard for operators and patients alike. Inhalation of aluminum oxide particles over time can result in serious respiratory disorders.

BRIEF DESCRIPTION OF THE DRAWINGS

FIGS. **1**A-**1**B are sectional illustrations of a patient's skin showing dermal layers.

FIG. **2** is a view of a Type "A" body and working end of the instrument of the invention.

FIG. **3** is an enlarged view of the working end of the instrument of FIG. **2**.

FIG. **4** is a sectional view of working end of FIG. **3**.

FIG. **5** is a view showing the manner of using the working end of the invention of FIGS. **3**-**4** in performing a method of the invention.

FIG. **6** is a view of a Type "B" body, working end and handle in an exploded view.

FIG. **7** is a view of the working end of the instrument of FIG. **6** and a housing.

FIG. **8** is an enlarged view of the skin interface of the working end of FIG. **7**.

FIG. **9** is a sectional view of the skin interface of FIG. **8**.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

1. Type "A" Skin Resurfacing System. Referring to FIGS. **2**-**3**, an exemplary instrument system **5** is shown for removing superficial skin layers. The instrument system **5** includes: (i) a hand-held body **18** with a working end **20** that defines a skin interface surface portion indicated at **25** in FIGS. **2**-**3**. An opening portion **26** transitions into an interior passageway **28** that extends through the body to communicate with a negative (−) pressure source (or aspiration source) indicated at **30** that operates as vacuum means for aspirating skin debris from a targeted skin surface treatment site TS.

Of particular interest, FIGS. **3**-**4** show views of the working end **20** with the skin interface **25** being configured with a particular irregular or ridged surface structure indicated at **32**. The ridged surface structure **32** further has a particular minimum width dimension W to accommodate from the ridge shape with as many as about **25** ridges on each side of opening **26** depending on the overall dimensions of the working end **20**. More particular aspects of the irregular or ridged surface structure **32** will be described below.

In this preferred embodiment, the working end **20** is of any suitable material, such as a transparent medical grade plastic. The transparency of the working end will assist the operator in localizing treatment in a particular targeted skin treatment area. The overall transverse dimension of the working end **20** of FIGS. **2**-**3** may be from around about 5.0 mm. to about 50.0 mm. with a larger dimensioned end being adapted for treating a larger skin area (e.g., arms, back legs and decolletage). A typical dimension is from about 5.0 mm. to 15.0 mm. for a skin treatment site area TS around a patient's face.

The invention allows the area (e.g., in mm^2) of opening **26** be in any selected shape but preferably is an elongate shape in the center of the working end **25**. The open distal end **26** comprises the distal termination of passageway **28** and the proximal end of the passageway in handle **18** is connected to a flexible aspiration tube **33** that extends to a remote collection reservoir **35** intermediate to the actual aspiration source **30**. The aspiration source **30** thus is adapted to draw the working end **20** and more particularly the skin interface **25** against the skin treatment site TS to perform the method of the invention as will be described below. The aspiration source or negative (−) pressurization source **30** may be any suitable vacuum source known in the art. Between the aspiration source **30** and remote collection reservoir **35** may be a filter **38** subsystem that is known in the art for collecting aspirated skin detritus and spent crystalline agents CA that are captured in the open distal end of passageway chamber **28**. The collection reservoir **35** and filter **38** are preferably of inexpensive plastic and other materials that are disposable.

The aspiration source **30** may be provided with an adjustable valve means **40** for adjusting the pressure level setting to any suitable range. The physician will learn from experience how to balance the pressure level to attain the desired level of suction against the patient's skin. A trigger or switch component **42** is provided as a foot-switch (FIG. **2**) but any suitable finger switch in the body **18** also may be used.

The working end **20** also carries means for introducing abrasive crystals into the working end or distalmost end of passageway **28** to allow individual loose crystalline agents CA to thereafter be captured between the skin interface **25** and the patient's skin. In this embodiment, two channels **44***a*-**44***b* are provided together with flexible tubes **46***a*-**46***b* to introduce the loose crystalline agents CA into the working end (see FIGS. **2**-**4**). Each distal portion **47** (collectively) of the channels **44***a*-**44***b* may comprise a small dimension aperture to limit the rate of flow of crystalline agents CA into the working end. The number of such channels (i.e., **44***a*-**44***n*) may range from one to about ten and fall within the scope of the invention. Any singular or plural number of channels can serve the purpose of slowly introducing crystal into the working end. Referring to FIGS. **2**-**3**, the crystalline agent CA delivery source **50** comprises a reservoir **55** that holds a suitable volume of abrasive crystals for a single treatment or a number of treatments. A flexible supply tube **56** extends between a remote the reservoir **55**, and in this embodiment the tube is split to connect to the two channels **44***a*-**44***b*. Preferably, the remote reservoir **55** that carries the crystalline agent CA is unpressurized but carries air intake relief valve **58** such

that any slight negative pressure created by the aspiration source **30** when the skin interface is in contact with a patient's skin will draw crystals to the working end. It should be appreciated that reservoir **55** may be built into handle body **18** and fall within the scope of the invention. The crystal delivery source **50** may carry crystals ranging in size from about 1 μm to about 50 μm in maximum cross-sectional dimension, (for example, aluminum oxide crystals). Preferably, the crystals are from about 5 μm to about 30 μm in maximum cross-sectional dimension to allow a very fine abrasion of the epidermis.

It has been found that by a slight negative pressure environment the open end **26** and passageway **28**, the crystalline agent will be caused to dribble into, or be sucked into, the passageway **28** in the working end **20**. Thereafter, the movement of the working end **20** in a sideways movement over the skin causes a portion of the crystalline agent CA volume to be captured temporarily in the irregular or corrugated surface structure of the skin interface **25**. In this process of moving the skin interface **25** over the targeted treatment site TS, it has been found that the sharp-edged crystalline agents are rolled over and over while being pressed into the surface of the skin and thereby abrade and remove the skin surface in a controllably gentle manner that is below any threshold of significant pain.

After the spent crystals are rolled over and over by the skin interface when moving in a first lateral direction across the skin, and after the working end is then is reversed in directional movement across the skin, a portion of the spent crystals and abraded skin debris necessarily roll into the central opening portion **26** wherein the negative pressure environment captures and aspirates the abraded materials to the remote collection reservoir **35**.

To facilitate the process described above, the invention is provided with novel aspects that relate to the irregular or ridged surface structure **32** mentioned above. The entire skin interface **25** may be of any suitable plan form (e.g., round, oval, rectangular etc.) and fall within the scope of the invention. More in particular, the interface **25** defines a 1^{st} outer periphery **25**A and a 2^{nd} inner periphery **25**B that generally are in apposition to one another and are spaced apart by width W with the inner periphery about the edge of opening **26** (see FIG. **3**).

In a preferred embodiment shown in FIGS. **3-4**, the concept of 1^{st} and 2^{nd} peripheries **25**A and **25**B in apposition thus comprise peripheries that are dual and side-by-side as shown in FIG. **4** and are thus adapted for side-to-side lateral or sideways movement while performing the technique of the invention, for example which is a natural movement of a human hand over a patient's skin. Thus, the direction of the ridges **60** extend generally transverse relative to a line drawn that indicates the direction of movement of the working end **20** in performing the method of the invention. That is, in the exemplary working end of FIG. **4**, the working end is generally optimized for side-to-side or lateral movement. Thus, the ridge alignment is generally transverse to the direction of movement in operations indicated by arrow A. (In a circular working end that is adapted generally for movement is any direction, the direction of the ridges **60** may be generally transverse to any direction of movement by being concentric relative to a central opening **26** (not shown)).

The terms irregular or ridged shape structure **32** as used herein mean that a series of at least one projecting edge portion **62***a* projects distally as a ridge within the skin interface portion **25**. The irregular shape structure **32** further typically carries recessed portions or valley portions **62***b* that are recessed in the proximal direction intermediate to any plurality of projecting edge portions **62***a*. These surface configurations for convenience are herein termed the primary shape structure (or ridge and valley elements). The width of the skin interface **25** containing shape structure **32** may be from about 2.0 mm. to 25.0 mm. or more and preferably is from about 3.0 mm. to 10.0 mm. The number of ridges preferably are from about 1 ridge to 25 ridges on each side of the opening **26**. The height H of any ridge from the apex of the projecting portion **62***a* to the depth of the valley portion **62***b* may be from about 0.25 mm. to about 5.0 mm. and is preferably from about 0.5 mm. to about 2.0 m. It has been found that various ridge height dimensions are optimal depending on the patient's skin type. Further, but optionally, it has been found that secondary shape structure of notches or recessed grooves **66** configured across the primary shape structure of ridge and valley elements may help introduce loose crystals to regions of the skin interface **25** in contact with the skin which is desirable. Such secondary grooves **66** are shown in FIG. **4** and are preferably somewhat in alignment with an axis of channels **44***a*-**44***b* that introduce crystals into the working end **20** thus allowing the crystals to be suctioned into the valleys **62***b* of the primary shape structure.

While the series of primary ridge and valley elements together the secondary grooves seems to be optimal for the method described below, it should be appreciated that the method also may be performed with a skin interface that has (i) only primary ridge and valley elements; (ii) or only a particular surface roughness that is appropriate for partially capturing loose crystals as will be described below-as long as the skin interface has a minimum width of about 3.0 mm. which was described as a preferred width dimension previously.

FIG. **4** further shows that at least some of the crests or apexes of some of the ridge portions **62***a* together with the outermost periphery of the skin interface **25** define an overall tissue-receiving shape **64** that may range from flat to concave and is shown in a preferred concave configuration. The alternative shapes **64***a*-**44***b* are intended to indicate an approximate range of shapes that are suitable. The apexes of ridges **62***a* need not all be at the same height to define shape **64**. The purpose of the concave shape is to cause the outer periphery of the working end to be in firm contact with the tissue surface while the negative pressure from aspiration source **30** draws the skin into firm contact with tissue interface **25**.

2. Practice of the Method of the Invention. Now turning to FIG. **5**, a sectional view of working end **20** shows the technique of the present invention in exfoliating or removing skin surface layers. FIG. **5** shows the working end **20** after actuation of the negative (−) pressure source **30** with the skin surface **70** initially being drawn into the concave shape **64**. The operating negative pressures may be in any suitable range that is determined by investigation. It has been found by experimentation that optimal pressure levels vary greatly depending on (i) the type of skin targeted for treatment, (ii) the dimensions across the working end, and (iii) the dimensions of opening **26**.

Next, the operator moves the skin interface **25** across a treatment site TS which is a path on the patient's skin while still actuating moves the trigger **42** thereby maintaining the negative pressure environment in the passageway **26**. The negative pressure environment within the working end causes crystalline particles and entrained in air to be drawn into passageway **28** proximate to the skin surface and into the shape structure **32** of the skin interface **25**. The sideways or lateral movement of the skin interface **25** captures a portion of the crystals between the interface and the skin surface, in part by over-rolling them. The continued rolling of the sharp-

edged crystals trapped between the instrument and the skin surface **70** causes an abrasion and removal of the skin surface in a controllable manner.

As working end is moved in a reverse direction, the negative pressure environment in the passageway **28** captures and aspirates the spent crystals and skin debris to the remote collection reservoir **35**. At the end of a particular lateral movement of the working end, the operator may release the trigger **42** which terminates the crystal agent delivery and further allows the operator to easily lift the working end from the patient's skin. The treated path can be easily seen and the operator then can exfoliate another slightly overlapping or adjacent path by repeating the above steps until surface removal is completed over the targeted treatment area.

3. Type "B" Skin Resurfacing System. Referring to FIGS. **6-9**, another exemplary instrument system and treatment device **205** is shown for removing superficial skin layers. This system differs greatly from the Type "A" embodiment in the mechanism of action that abrades the skin since the Type "B" system uses a fluid media plus an abrading structure on the skin interface. Still several features of the Type "B" embodiment are similar to the Type "A" embodiment and the two modalities of treatment may be used to complement one another.

FIG. **6** shows that a hand-held instrument **208** has a removable working end **220** that defines a skin interface surface portion indicated at **225**. Handle portion **227***a* mates with housing **227***b*. A flexible tube **228** extends to a vacuum source **230**. A fluid reservoir **235** carrying a fluid skin treatment media is housed in the handle although it could also be a remote reservoir.

Referring now to FIGS. **7-9**, a first aperture arrangement consisting of at least one port or opening portion **240** of skin interface **225** that communicates with an interior passageway **242** that extends through housing **227***b* to hose **228** and the vacuum or negative (−) pressure source.

FIGS. **7-9** further show a second aperture arrangement in the skin interface consisting of at least one port or openings **250** that extend around an outer periphery of the skin interface **225**. These opening(s) of the second aperture arrangement are in fluid communication with the reservoir **235** and the treatment media therein. The skin interface has a series of primary ridge elements **255***a* and valley elements **255***b* together the secondary notches or grooves **260** as defined above with similar dimensional parameters. This embodiment differs however in that the apexes of ridge elements **255***a* are substantially a sharp edge as are the edged of the notches **260**. Thus, these primary surface elements **255***a* and secondary surface elements thereby define teeth therebetween that seem well suited to abrading skin layers particularly after being hydrated by the fluid source of the system. Experimentation has shown that the vacuum source and fluid source may be reversed between the first and second aperture arrangements **240** and **250** with the method of skin removal still working well. The vacuum system aspirates away skin debris and spent fluids as described previously. Of particular interest, the method of the invention appears to work well because the suction on the skin treatment site very quickly hydrated, or puffs up, the skin which in turn make the surface layer susceptible to painless abrasion. The ability of the system to rapidly deliver fluids to subsurface tissues allows the use of any pharmacological agent known in the art for enhancing skin rejuvenation as a part of the skin treatment. The system can use sterile water or saline solution for a treatment to remove dermal tissue with the abrasive surface of the treatment device. The system can also use a fluid carrying a chemical agent of a suitable concentration be selected from a group of acids including TCA (trichloroacetic acid), a glycolic acid including an alphahydroxy acid (AHA), a lactic acid, a citric acid, or phenol as disclosed in co-pending U.S. patent application Ser. No. 09/524,731 filed Mar. 14, 2000 which is incorporated herein by this reference.

Specific features of the invention may be shown in some figures and not in others, and this is for convenience only and any feature may be combined with another in accordance with the invention. While the principles of the invention have been made clear in the exemplary embodiments, it will be obvious to those skilled in the art that modifications of the structure, arrangement, proportions, elements, and materials may be utilized in the practice of the invention, and otherwise, which are particularly adapted to specific environments and operative requirements without departing from the principles of the invention. The appended claims are intended to cover and embrace any and all such modifications, with the limits only of the true purview, spirit and scope of the invention.

What is claimed is:

1. A method for abrading skin of a patient, comprising:

(a) placing a working end of a skin treatment device against the skin of the patient;

(b) drawing the skin against an abrading surface on a skin interface on the working end of the skin treatment device by applying suction to the skin through an aspiration opening in the working end, the abrading surface comprising apexes extending upwardly from the abrading surface and the apexes having sharp edges;

(c) moving the treatment device across the skin while the sharp edge of the apexes remain stationary with respect to the working end of the skin treatment device;

(d) abrading the skin drawn against the sharp edge of the apexes while continuously applying suction through the aspiration opening; and

(e) removing skin debris through the aspiration opening in the working end of the skin treatment device.

2. The method of claim **1**, further comprising providing a fluid to the skin.

3. The method of claim **2**, wherein the fluid is provided with a crystalline abrasive.

4. The method of claim **2**, wherein the fluid hydrates the skin.

5. The method of claim **2**, wherein the fluid is provided with a pharmacologically-active agent for treating skin.

6. The method of claim **2**, wherein the fluid is provided with an agent selected from the class consisting of citric acid and lactic acid.

7. The method of claim **2**, wherein the fluid is provided with an agent selected from the class comprising TCA (trichloroacetic acid), glycolic acid, alphahydroxy acid (AHA).

8. The method of claim **3**, wherein providing a fluid to the skin the fluid further comprises providing through a fluid opening provided in the working end of the skin treatment device.

9. The method of claim **2**, further comprising providing sterile water or saline solution to the skin.

* * * * *

EXHIBIT 3

US007789886B2

(12) **United States Patent**
Shadduck

(10) **Patent No.: US 7,789,886 B2**
(45) **Date of Patent: *Sep. 7, 2010**

(54) **INSTRUMENTS AND TECHNIQUES FOR CONTROLLED REMOVAL OF EPIDERMAL LAYERS**

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(73) Assignee: **Axia MedSciences, LLC**, Tiburon, CA (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 1656 days.

This patent is subject to a terminal disclaimer.

(21) Appl. No.: **10/699,747**

(22) Filed: **Nov. 3, 2003**

(65) **Prior Publication Data**

US 2004/0143274 A1 Jul. 22, 2004

Related U.S. Application Data

(63) Continuation of application No. 09/648,025, filed on Aug. 25, 2000, now Pat. No. 6,641,591.

(60) Provisional application No. 60/150,782, filed on Aug. 26, 1999.

(51) **Int. Cl.**
A61B 17/50 (2006.01)
A61B 17/06 (2006.01)

(52) **U.S. Cl.** **606/131**

(58) **Field of Classification Search** 606/131, 606/132, 133; 604/289
See application file for complete search history.

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File History of Reissue U.S. Appl. No. 11/027,590, filed Dec. 29, 2004 (Reissue of U.S. Patent No. 6,500,183, issued Dec. 31, 2002).

(Continued)

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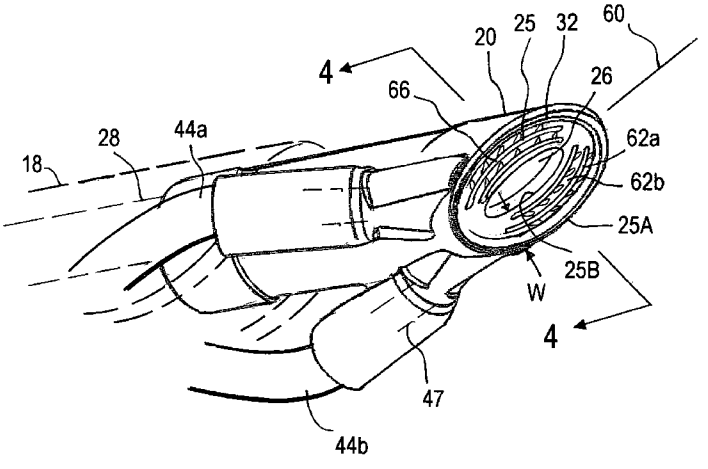
(57) **ABSTRACT**

An instrument and technique for the removal of epidermal layers in a controlled manner utilizing a hand-held instrument with a working end that (i) a vacuum aspiration system, (ii) a source for delivery of a sterile fluids or pharmacological agents to the skin; and (iii) a skin interface surface in the working end that has specially shape structure for abrading surface layers of the patient's epidermis as the working end is moved over the patient's skin while at the same time causing rapid penetration of the fluids into the skin for therapeutic purposes. Movement of the working end across the skin causes abrasion of the surface layers in a path over the patient's skin. The method of the invention may be used in a periodic treatment for the removal of superficial skin layers that enhances the synthesis of dermal collagen aggregates by inducing the body's natural wound healing response. The method of the invention creates more normal dermal architectures in skin with limited depths of skin removal by the series of superficial treatments that may be comparable to the extent of neocollagenesis caused by a deep skin removal treatment (e.g., CO_2 laser skin removal).

16 Claims, 9 Drawing Sheets



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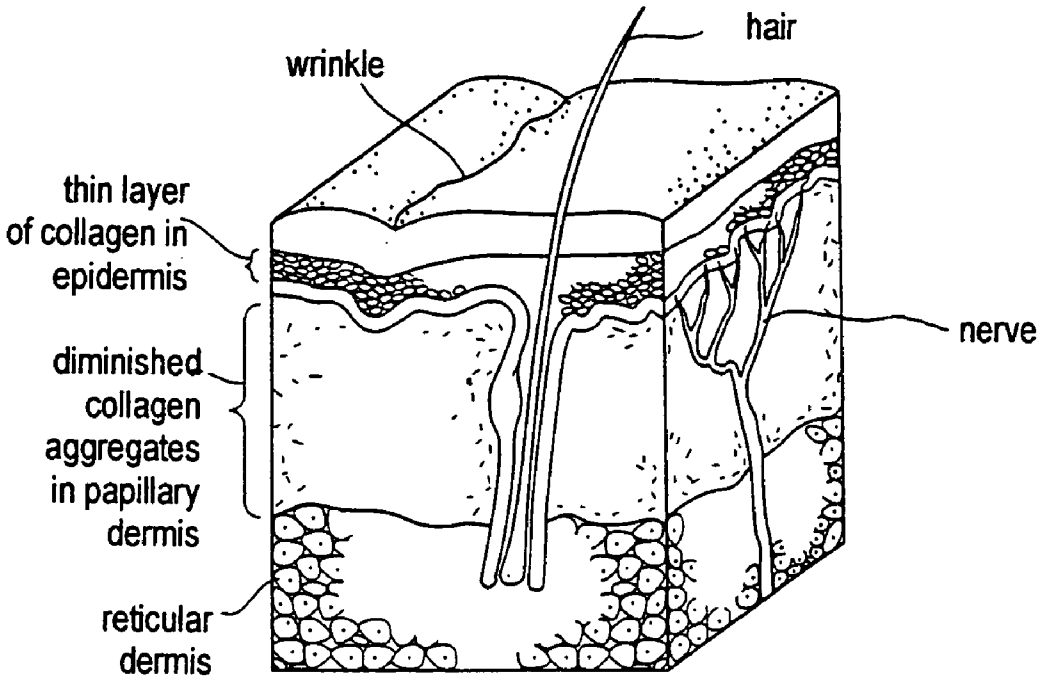
hair
wrinkle
thin layer of collagen in epidermis
diminished collagen aggregates in papillary dermis
reticular dermis
nerve

FIG. 1A

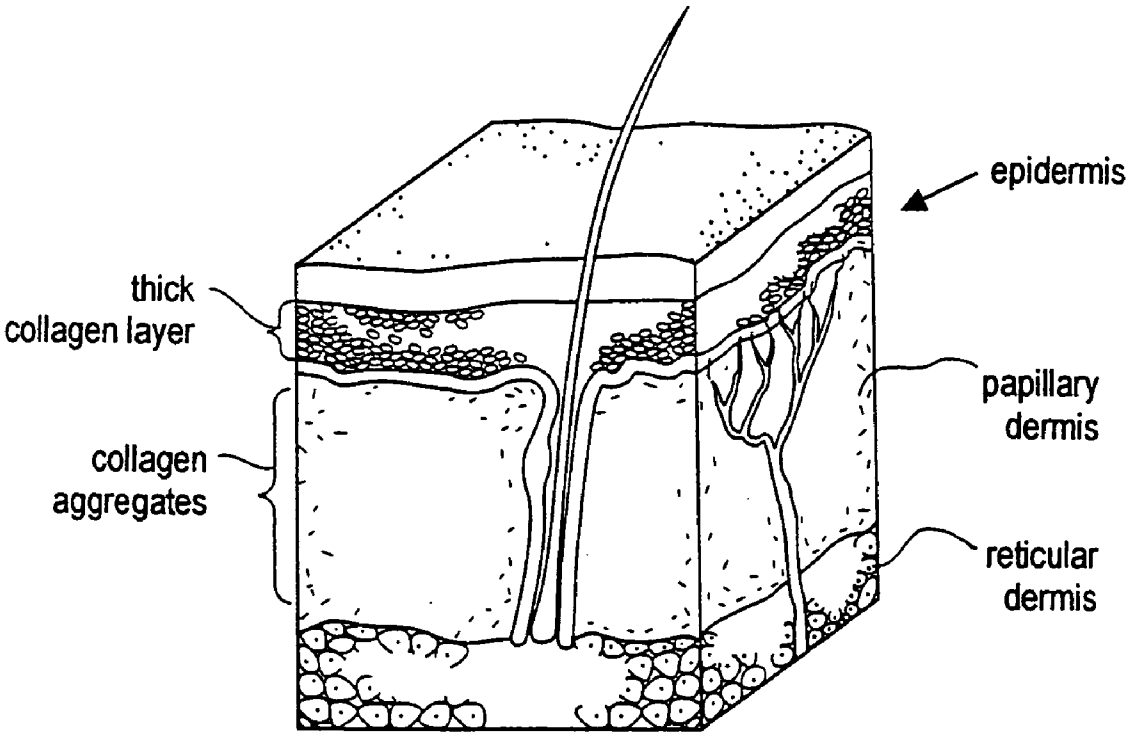
epidermis
thick collagen layer
collagen aggregates
papillary dermis
reticular dermis

FIG. 1B

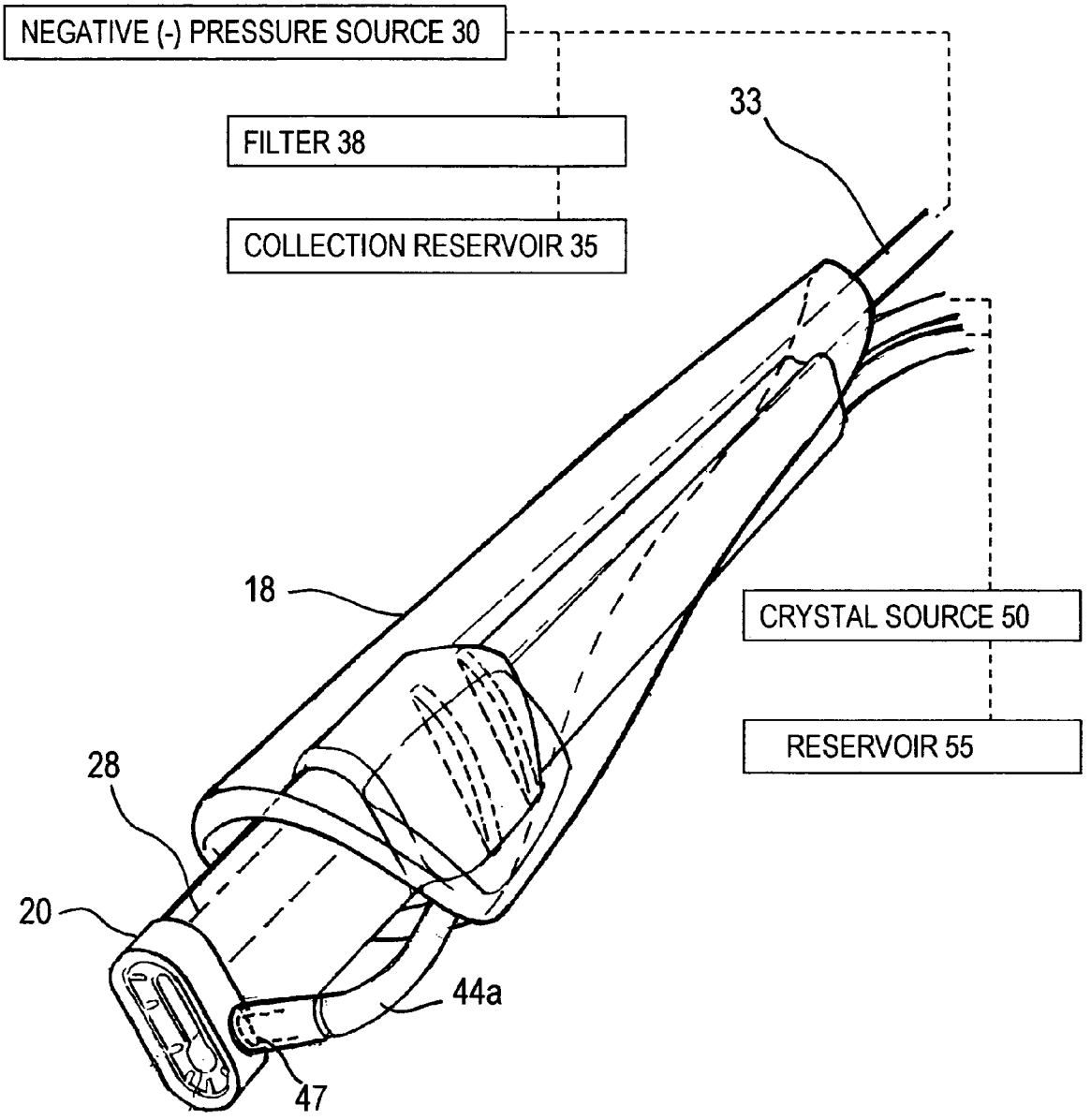
NEGATIVE (-) PRESSURE SOURCE 30
FILTER 38
COLLECTION RESERVOIR 35
33
18
CRYSTAL SOURCE 50
RESERVOIR 55
28
20
44a
47

FIG. 2

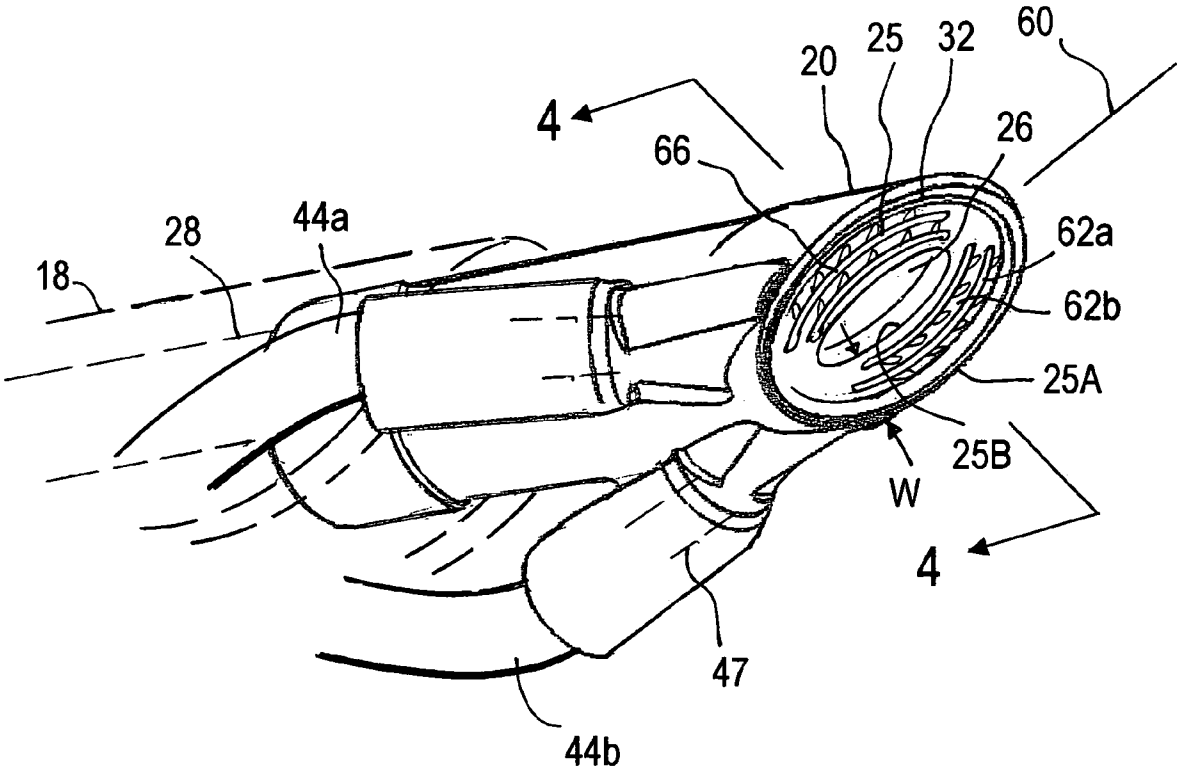

FIG. 3

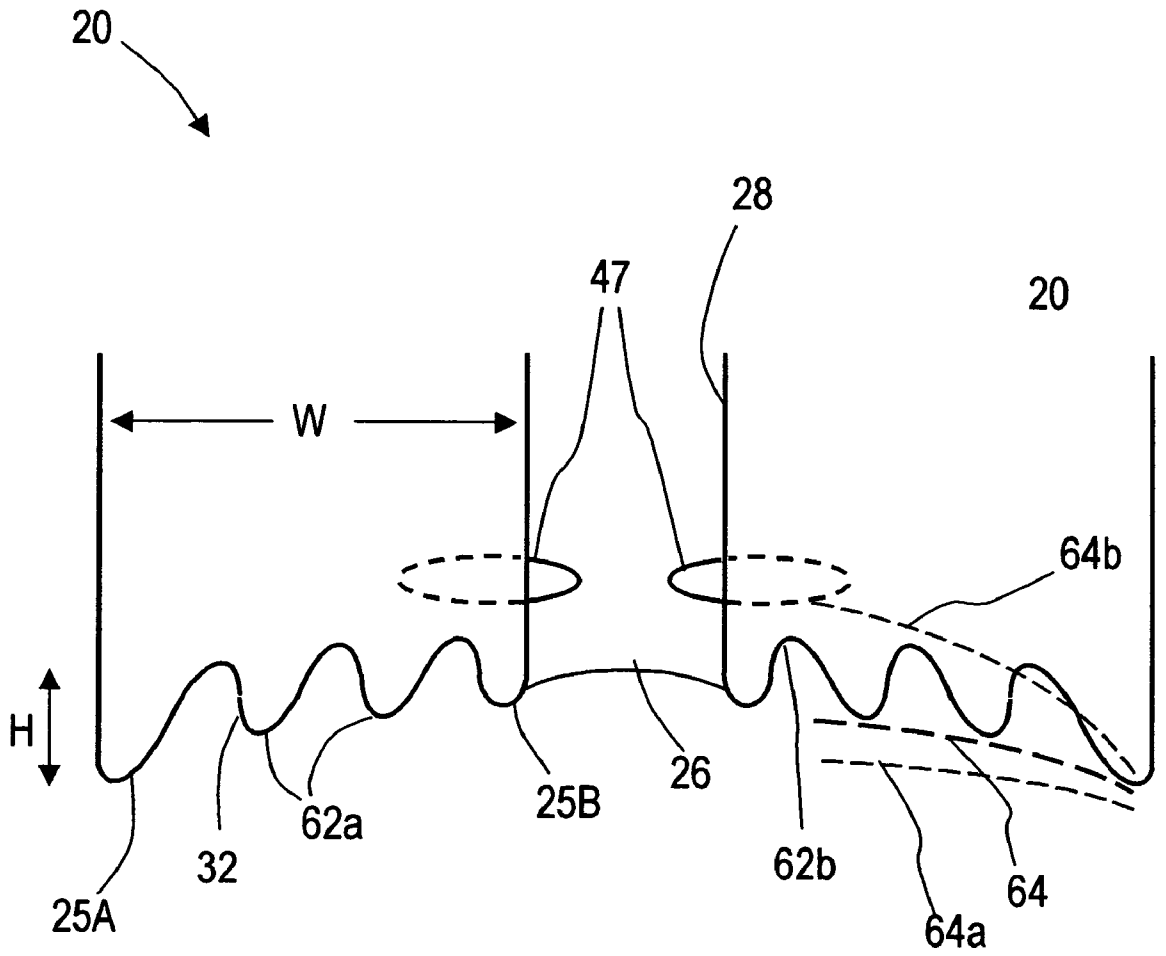

FIG. 4

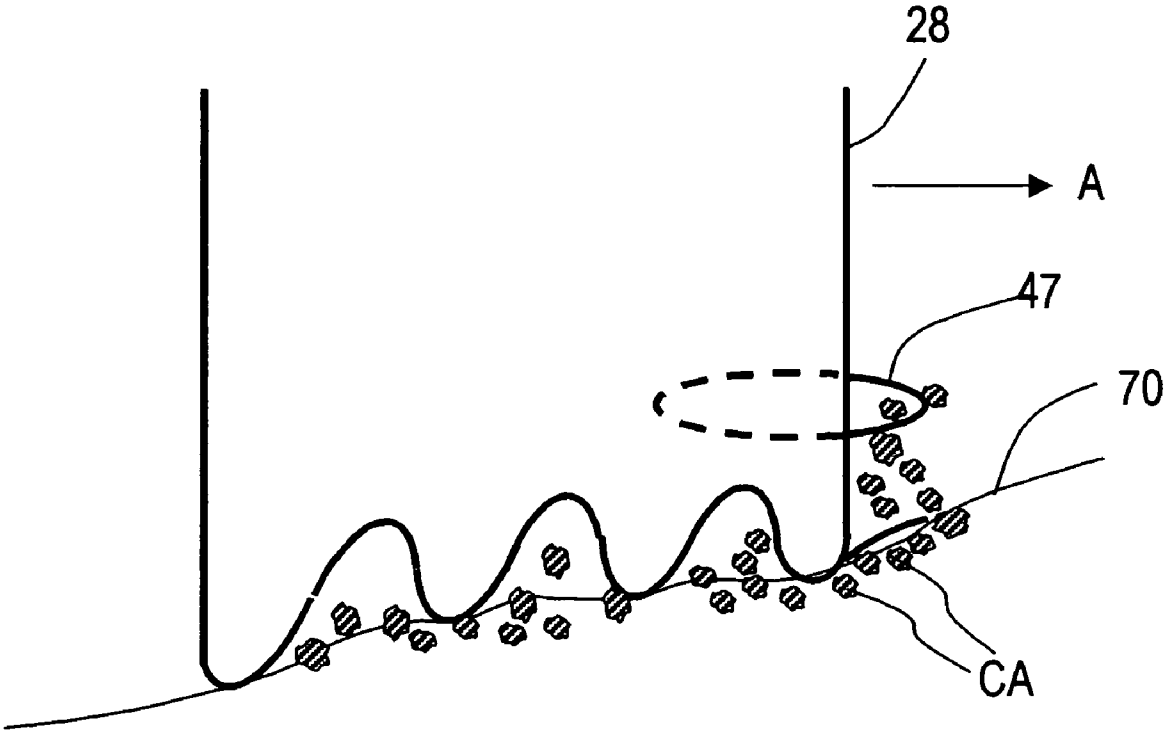

FIG. 5

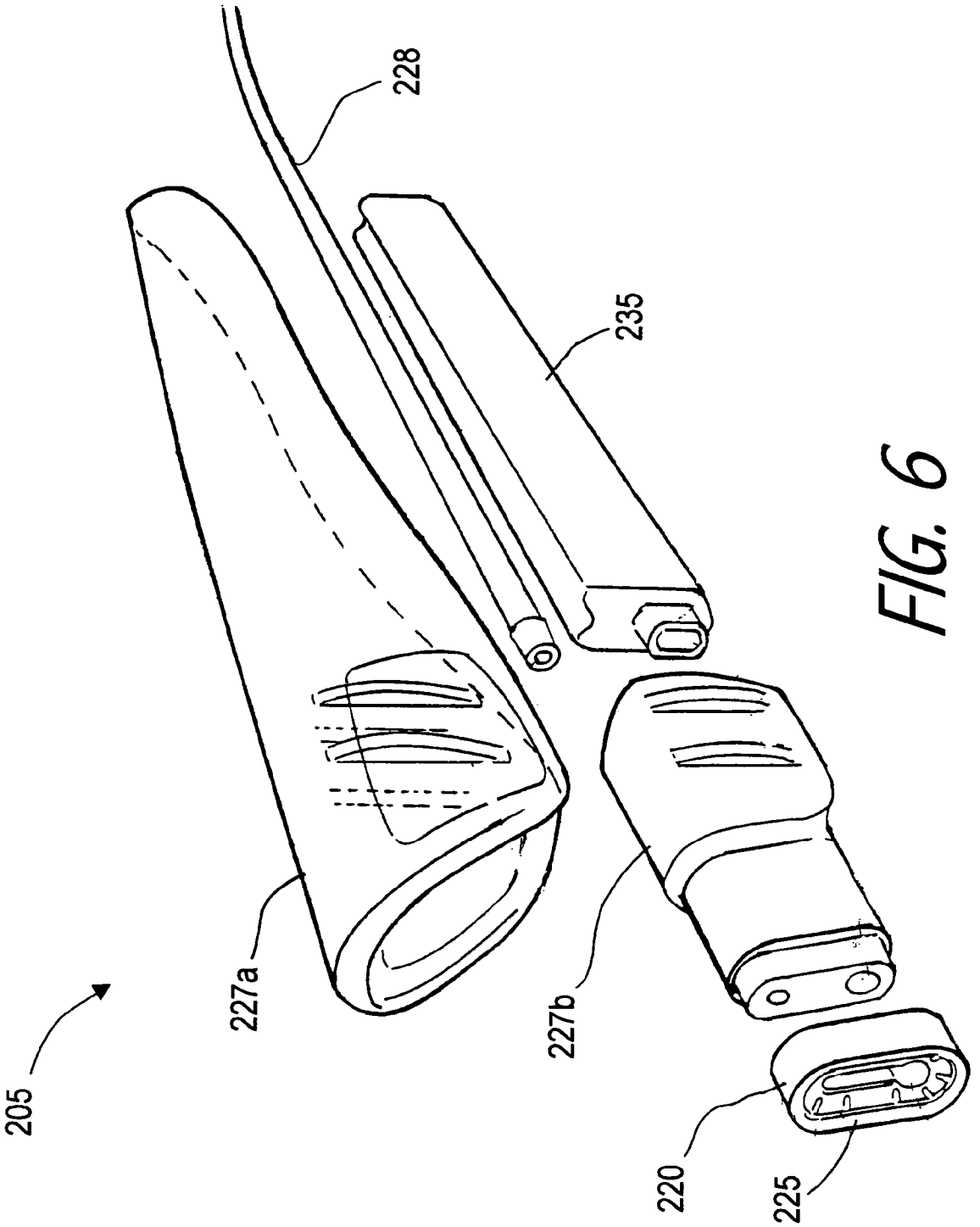

FIG. 6

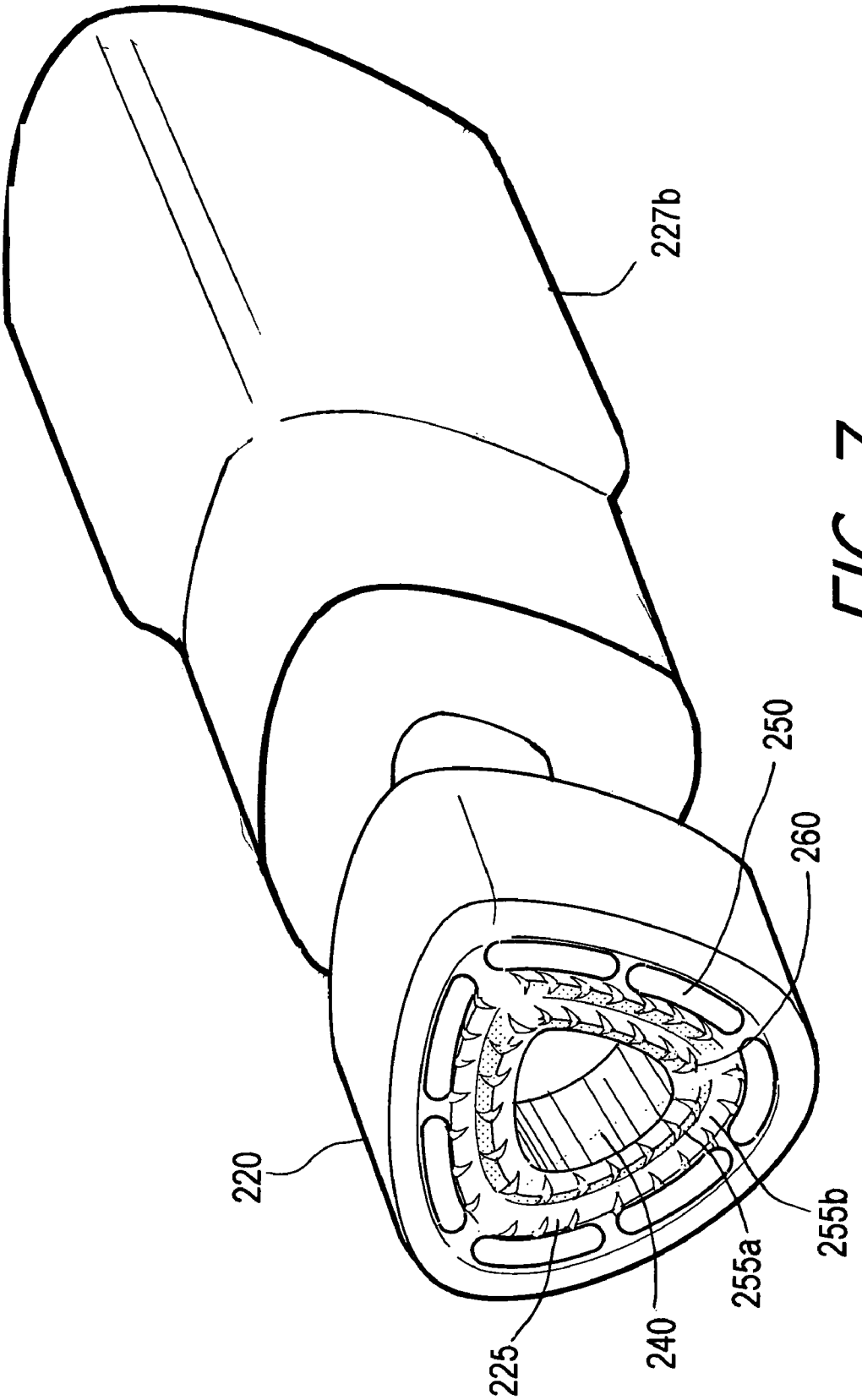

FIG. 7

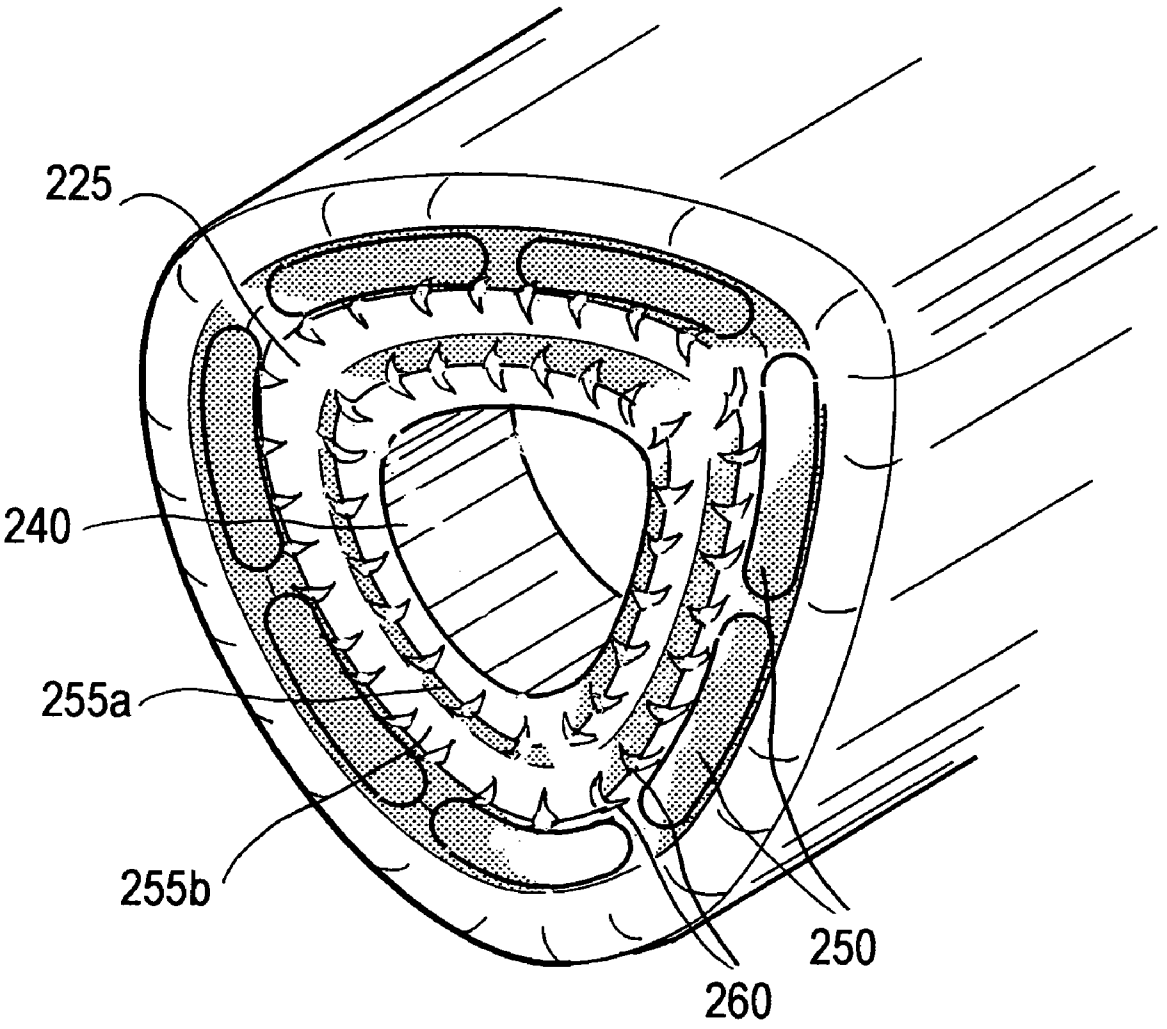

FIG. 8

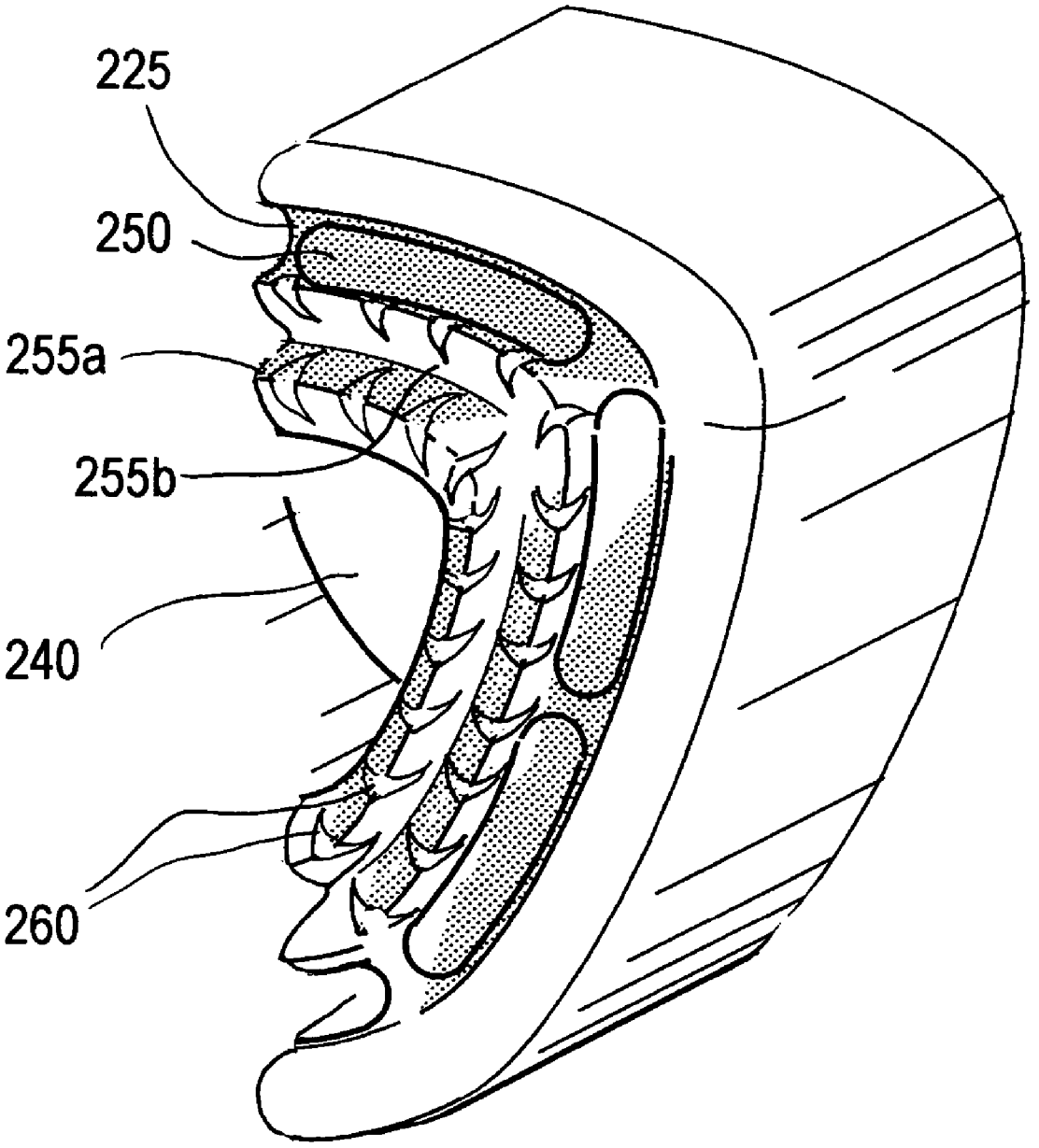

FIG. 9

INSTRUMENTS AND TECHNIQUES FOR CONTROLLED REMOVAL OF EPIDERMAL LAYERS

CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a continuation of U.S. patent application Ser. No. 09/648,025 filed Aug. 25, 2000 now U.S. Pat. No. 6,641,591, which claims benefit of Provisional U.S. Patent Application Ser. No. 60/150,782 filed Aug. 26, 1999.

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates to devices for dermatology and more particularly to a hand-held instrument with a working end that carries (i) a negative pressure aspiration system, (ii) a source for delivery of a sterile fluids to the skin; and (iii) a skin interface surface in the working end that has specially shape structure for abrading surface layers of the patient's epidermis as the working end is moved over the patient's skin while at the same time causing rapid penetration of the fluids into the skin for therapeutic purposes.

2. Description of Background Art

Dermatologists and plastic surgeons have used various methods for removing superficial skin layers to cause the growth of new skin layers (i.e., commonly described as skin resurfacing techniques) since the early 1900's. Early skin resurfacing treatments used an acid such as phenol to etch away surface layers of a patient's skin that contained damage to thereafter be replaced by new skin. (The term damage when referring to a skin disorder is herein defined as any cutaneous defect, e.g., including but not limited to rhytides, hyperpigmentation, acne scars, solar elastosis, other dyschromias, stria distensae, seborrheic dermatitus).

Following the removal of surface skin layers at a particular depth, no matter the method of skin removal, the body's natural wound-healing response begins to regenerate the epidermis and underlying wounded skin layers. The new skin layer will then cytologically and architecturally resemble a younger and more normal skin. The range of resurfacing treatments can be divided generally into three categories based on the depth of the skin removal and wound: (i) superficial exfoliations or peels extending into the epidermis, (ii) medium-depth resurfacing treatments extending into the papillary dermis, and (iii) deep resurfacing treatments that remove tissue to the depth of the reticular dermis (see FIGS. **1**A-**1**B).

Modern techniques for skin layer removal include: CO_2 laser resurfacing which falls into the category of a deep resurfacing treatment; Erbium laser resurfacing which generally is considered a medium-depth treatment; mechanical dermabrasion using high-speed abrasive wheels which results in a medium-depth or deep resurfacing treatment; and chemical peels which may range from a superficial to a deep resurfacing treatment, depending on the treatment parameters. A recent treatment, generally called micro-dermabrasion, has been developed that uses an air-pressure source to deliver abrasive particles directly against a patient's skin at high-velocities to abrade away skin layers. Such a micro-dermabrasion modality may be likened to sandblasting albeit at velocities that do no cause excess pain and discomfort to the patient. Micro-dermabrasion as currently practiced falls into the category of a superficial resurfacing treatment.

A superficial exfoliation, peel or abrasion removes some or all of the epidermis (see FIGS. **1**A-**1**B) and thus is suited for

treating very light rhytides. Such a superficial exfoliation is not effective in treating many forms of damage to skin. A medium-depth resurfacing treatment that extends into the papillary dermis (see FIG. **1**B) can treat many types of damage to skin. Deep resurfacing treatments, such as CO_2 laser treatments, that extend well into the reticular dermis (see FIG. **1**B) causes the most significant growth of new skin layers but carry the risk of scarring unless carefully controlled.

It is useful to briefly explain the body's mechanism of actually resurfacing skin in response to the removal of a significant depth of dermal layers. Each of the above-listed depths of treatment disrupts the epidermal barrier, or a deeper dermal barrier (papillary or reticular), which initiates varied levels of the body's wound-healing response. A superficial skin layer removal typically causes a limited wound-healing response, including a transient inflammatory response and limited collagen synthesis within the dermis. In a medium-depth or a deep treatment, the initial inflammatory stage leads to hemostasis through an activated coagulation cascade. Chemotactic factors and fibrin lysis products cause neutrophils and monocytes to appear at the site of the wound. The neutrophils sterilize the wound site and the monocytes convert to macrophages and elaborate growth factors which initiate the next phase of the body's wound-healing response involving granular tissue formation. In this phase, fibroblasts generate a new extracellular matrix, particularly in the papillary and reticuilar dermis, which is sustained by angiogenesis and protected anteriorly by the reforming epithelial layer. The new extracellular matrix is largely composed of collagen fibers (particularly Types I and III) which are laid down in compact parallel arrays (see FIG. **1**B). It is largely the collagen fibers that provide the structural integrity of the new skin—and contribute to the appearance of youthful skin.

All of the prevalent types of skin damage (rhytides, solar elastosis effects, hyperpigmentation, acne scars, dyschromias, melasma, stria distensae) manifest common histologic and ultrastructural characteristics, which in particular include disorganized and thinner collagen aggregates, abnormalities in elastic fibers, and abnormal fibroblasts, melanocytes and keratinocytes that disrupt the normal architecture of the dermal layers. It is well recognized that there will be a clinical improvement in the condition and appearance of a patient's skin when a more normal architecture is regenerated by the body's wound-healing response. Of most significance to a clinical improvement is skin is the creation of more dense parallel collagen aggregates with decreased periodicity (spacing between fibrils). The body's wound-healing response is responsible for synthesis of these collagen aggregates. In addition to the body's natural wound healing response, adjunct pharmaceutical treatments that are administered concurrent with, or following, a skin exfoliations can enhance the development of collagen aggregates to provide a more normal dermal architecture in the skin—the result being a more youthful appearing skin.

The deeper skin resurfacing treatments, such as laser ablation, chemical peels and mechanical dermabrasion have drawbacks. The treatments are best used for treatments of a patient's face and may not be suited for treating other portions of a patient's body. For example, laser resurfacing of a patient's neck or decolletage may result in post-treatment pigmentation disorders. All the deep resurfacing treatments are expensive, require anesthetics, and must be performed in a clinical setting. Perhaps, the most significant disadvantage to deep resurfacing treatments relates to the post-treatment recovery period. It may require up to several weeks or even months to fully recover and to allow the skin the form a new epidermal layer. During a period ranging from a few weeks to

several weeks after a deep resurfacing treatment, the patient typically must wear heavy make-up to cover redness thus making the treatment acceptable only to women.

The superficial treatment offered by micro-dermabrasion has the advantages of being performed without anesthetics and requiring no extended post-treatment recovery period. However, micro-dermabrasion as currently practices also has several disadvantages. First, a micro-dermabrasion treatment is adapted only for a superficial exfoliation of a patient's epidermis which does not treat many forms of damage to skin. Further, the current micro-dermabrasion devices cause abrasive effects in a focused area of the skin that is very small, for example a few $mm.^2$, since all current devices use a single pin-hole orifice that jets air and abrasives to strike the skin in a highly focused area. Such a focused treatment area is suitable for superficial exfoliations when the working end of the device is passed over the skin in overlapping paths. Further, such focused energy delivery is not well suited for deeper skin removal where repeated passes may be necessary. Still further, current micro-dermabrasion devices are not suited for deeper skin removal due to the pain associated with deep abrasions. Other disadvantages of the current micro-dermabrasion devices relate to the aluminum oxide abrasive particles that are typically used. Aluminum oxide can contaminate the working environment and create a health hazard for operators and patients alike. Inhalation of aluminum oxide particles over time can result in serious respiratory disorders.

BRIEF DESCRIPTION OF THE DRAWINGS

FIGS. **1**A-**1**B are sectional illustrations of a patient's skin showing dermal layers.

FIG. **2** is a view of a Type "A" body and working end of the instrument of the invention.

FIG. **3** is an enlarged view of the working end of the instrument of FIG. **2**.

FIG. **4** is a sectional view of working end of FIG. **3**.

FIG. **5** is a view showing the manner of using the working end of the invention of FIGS. **3**-**4** in performing a method of the invention.

FIG. **6** is a view of a Type "B" body, working end and handle in an exploded view.

FIG. **7** is a view of the working end of the instrument of FIG. **6** and a housing.

FIG. **8** is an enlarged view of the skin interface of the working end of FIG. **7**.

FIG. **9** is a sectional view of the skin interface of FIG. **8**.

DETAILED DESCRIPTION OF THE INVENTION

1. Type "A" Skin Resurfacing System. Referring to FIGS. **2**-**3**, an exemplary instrument system **5** is shown for removing superficial skin layers. The instrument system **5** includes: (i) a hand-held body **18** with a working end **20** that defines a skin interface surface portion indicated at **25** in FIGS. **2**-**3**. An opening portion **26** transitions into an interior passageway **28** that extends through the body to communicate with a negative (−) pressure source (or aspiration source) indicated at **30** that operates as vacuum means for aspirating skin debris from a targeted skin surface treatment site TS.

Of particular interest, FIGS. **3**-**4** show views of the working end **20** with the skin interface **25** being configured with a particular irregular or ridged surface structure indicated at **32**. The ridged surface structure **32** further has a particular minimum width dimension W to accommodate from the ridge shape with as many as about 25 ridges on each side of opening **26** depending on the overall dimensions of the working end **20**. More particular aspects of the irregular or ridged surface structure **32** will be described below.

In this preferred embodiment, the working end **20** is of any suitable material, such as a transparent medical grade plastic. The transparency of the working end will assist the operator in localizing treatment in a particular targeted skin treatment area. The overall transverse dimension of the working end **20** of FIGS. **2**-**3** may be from around about 5.0 mm. to about 50.0 mm. with a larger dimensioned end being adapted for treating a larger skin area (e.g., arms, back legs and decolletage). A typical dimension is from about 5.0 mm. to 15.0 mm. for a skin treatment site area TS around a patient's face.

The invention allows the area (e.g., in $mm.^2$) of opening **26** be in any selected shape but preferably is an elongate shape in the center of the working end **25**. The open distal end **26** comprises the distal termination of passageway **28** and the proximal end of the passageway in handle **18** is connected to a flexible aspiration tube **33** that extends to a remote collection reservoir **35** intermediate to the actual aspiration source **30**. The aspiration source **30** thus is adapted to draw the working end **20** and more particularly the skin interface **25** against the skin treatment site TS to perform the method of the invention as will be described below. The aspiration source or negative (−) pressurization source **30** may be any suitable vacuum source known in the art. Between the aspiration source **30** and remote collection reservoir **35** may be a filter **38** subsystem that is known in the art for collecting aspirated skin detritus and spent crystalline agents CA that are captured in the open distal end of passageway chamber **28**. The collection reservoir **35** and filter **38** are preferably of inexpensive plastic and other materials that are disposable.

The aspiration source **30** may be provided with an adjustable valve means **40** for adjusting the pressure level setting to any suitable range. The physician will learn from experience how to balance the pressure level to attain the desired level of suction against the patient's skin. A trigger or switch component **42** is provided as a foot-switch (FIG. **2**) but any suitable finger switch in the body **18** also may be used.

The working end **20** also carries means for introducing abrasive crystals into the working end or distalmost end of passageway **28** to allow individual loose crystalline agents CA to thereafter be captured between the skin interface **25** and the patient's skin. In this embodiment, two channels **44***a*-**44***b* are provided together with flexible tubes **46***a*-**46***b* to introduce the loose crystalline agents CA into the working end (see FIGS. **2**-**4**). Each distal portion **47** (collectively) of the channels **44***a*-**44***b* may comprise a small dimension aperture to limit the rate of flow of crystalline agents CA into the working end. The number of such channels (i.e., **44***a*-**44***n*) may range from one to about ten and fall within the scope of the invention. Any singular or plural number of channels can serve the purpose of slowly introducing crystal into the working end, Referring to FIGS. **2**-**3**, the crystalline agent CA delivery source **50** comprises a reservoir **55** that holds a suitable volume of abrasive crystals for a single treatment or a number of treatments. A flexible supply tube **56** extends between a remote the reservoir **55**, and in this embodiment the tube is split to connect to the two channels **44***a*-**44***b*. Preferably, the remote reservoir **55** that carries the crystalline agent CA is unpressurized but carries air intake relief valve **58** such that any slight negative pressure created by the aspiration source **30** when the skin interface is in contact with a patient's skin will draw crystals to the working end. It should be appreciated that reservoir **55** may be built into handle body **18** and fall within the scope of the invention. The crystal delivery source **50** may carry crystals ranging in size from about 1 μm to about 50 μm in maximum cross-sectional dimension, (for

example, aluminum oxide crystals). Preferably, the crystals are from about 5 μm to about 30 μm in maximum cross-sectional dimension to allow a very fine abrasion of the epidermis.

It has been found that by a slight negative pressure environment the open end **26** and passageway **28**, the crystalline agent will be caused to dribble into, or be sucked into, the passageway **28** in the working end **20**. Thereafter, the movement of the working end **20** in a sideways movement over the skin causes a portion of the crystalline agent CA volume to be captured temporarily in the irregular or corrugated surface structure of the skin interface **25**. In this process of moving the skin interface **25** over the targeted treatment site TS, it has been found that the sharp-edged crystalline agents are rolled over and over while being pressed into the surface of the skin and thereby abrade and remove the skin surface in a controllably gentle manner that is below any threshold of significant pain.

After the spent crystals are rolled over and over by the skin interface when moving in a first lateral direction across the skin, and after the working end is then is reversed in directional movement across the skin, a portion of the spent crystals and abraded skin debris necessarily roll into the central opening portion **26** wherein the negative pressure environment captures and aspirates the abraded materials to the remote collection reservoir **35**.

To facilitate the process described above, the invention is provided with novel aspects that relate to the irregular or ridged surface structure **32** mentioned above. The entire skin interface **25** may be of any suitable plan form (e.g., round, oval, rectangular etc.) and fall within the scope of the invention. More in particular, the interface **25** defines a 1st outer periphery **25**A and a 2nd inner periphery **25**B that generally are in apposition to one another and are spaced apart by width W with the inner periphery about the edge of opening **26** (see FIG. **3**).

In a preferred embodiment shown in FIGS. **3-4**, the concept of 1st and 2nd peripheries **25**A and **25**B in apposition thus comprise peripheries that are dual and side-by-side as shown in FIG. **4** and are thus adapted for side-to-side lateral or sideways movement while performing the technique of the invention, for example which is a natural movement of a human hand over a patient's skin. Thus, the direction of the ridges **60** extend generally transverse relative to a line drawn that indicates the direction of movement of the working end **20** in performing the method of the invention. That is, in the exemplary working end of FIG. **4**, the working end is generally optimized for side-to-side or lateral movement. Thus, the ridge alignment is generally transverse to the direction of movement in operations indicated by arrow A. (In a circular working end that is adapted generally for movement is any direction, the direction of the ridges **60** may be generally transverse to any direction of movement by being concentric relative to a central opening **26** (not shown)).

The terms irregular or ridged shape structure **32** as used herein mean that a series of at least one projecting edge portion **62***a* projects distally as a ridge within the skin interface portion **25**. The irregular shape structure **32** further typically carries recessed portions or valley portions **62***b* that are recessed in the proximal direction intermediate to any plurality of projecting edge portions **62***a*. These surface configurations for convenience are herein termed the primary shape structure (or ridge and valley elements). The width of the skin interface **25** containing shape structure **32** may be from about 2.0 mm. to 25.0 mm. or more and preferably is from about 3.0 mm. to 10.0 mm. The number of ridges preferably are from about 1 ridge to 25 ridges on each side of the opening **26**. The height H of any ridge from the apex of the projecting portion **62***a* to the depth of the valley portion **62***b* may be from about 0.25 mm. to about 5.0 mm. and is preferably from about 0.5 mm. to about 2.0 m. It has been found that various ridge height dimensions are optimal depending on the patient's skin type. Further, but optionally, it has been found that secondary shape structure of notches or recessed grooves **66** configured across the primary shape structure of ridge and valley elements may help introduce loose crystals to regions of the skin interface **25** in contact with the skin which is desirable. Such secondary grooves **66** are shown in FIG. **4** and are preferably somewhat in alignment with an axis of channels **44***a*-**44***b* that introduce crystals into the working end **20** thus allowing the crystals to be suctioned into the valleys **62***b* of the primary shape structure.

While the series of primary ridge and valley elements together the secondary grooves seems to be optimal for the method described below, it should be appreciated that the method also may be performed with a skin interface that has (i) only primary ridge and valley elements; (ii) or only a particular surface roughness that is appropriate for partially capturing loose crystals as will be described below-as long as the skin interface has a minimum width of about 3.0 mm. which was described as a preferred width dimension previously.

FIG. **4** further shows that at least some of the crests or apexes of some of the ridge portions **62***a* together with the outermost periphery of the skin interface **25** define an overall tissue-receiving shape **64** that may range from flat to concave and is shown in a preferred concave configuration. The alternative shapes **64***a*-**44***b* are intended to indicate an approximate range of shapes that are suitable. The apexes of ridges **62***a* need not all be at the same height to define shape **64**. The purpose of the concave shape is to cause the outer periphery of the working end to be in firm contact with the tissue surface while the negative pressure from aspiration source **30** draws the skin into firm contact with tissue interface **25**.

2. Practice of the Method of the Invention. Now turning to FIG. **5**, a sectional view of working end **20** shows the technique of the present invention in exfoliating or removing skin surface layers. FIG. **5** shows the working end **20** after actuation of the negative (−) pressure source **30** with the skin surface **70** initially being drawn into the concave shape **64**. The operating negative pressures may be in any suitable range that is determined by investigation. It has been found by experimentation that optimal pressure levels vary greatly depending on (i) the type of skin targeted for treatment, (ii) the dimensions across the working end, and (iii) the dimensions of opening **26**.

Next, the operator moves the skin interface **25** across a treatment site TS which is a path on the patient's skin while still actuating moves the trigger **42** thereby maintaining the negative pressure environment in the passageway **26**. The negative pressure environment within the working end causes crystalline particles and entrained in air to be drawn into passageway **28** proximate to the skin surface and into the shape structure **32** of the skin interface **25**. The sideways or lateral movement of the skin interface **25** captures a portion of the crystals between the interface and the skin surface, in part by over-rolling them. The continued rolling of the sharp-edged crystals trapped between the instrument and the skin surface **70** causes an abrasion and removal of the skin surface in a controllable manner.

As working end is moved in a reverse direction, the negative pressure environment in the passageway **28** captures and aspirates the spent crystals and skin debris to the remote collection reservoir **35**. At the end of a particular lateral move-

ment of the working end, the operator may release the trigger **42** which terminates the crystal agent delivery and further allows the operator to easily lift the working end from the patient's skin. The treated path can be easily seen and the operator then can exfoliate another slightly overlapping or adjacent path by repeating the above steps until surface removal is completed over the targeted treatment area.

3. Type "B" Skin Resurfacing System. Referring to FIGS. **6-9**, another exemplary instrument system and treatment device **205** is shown for removing superficial skin layers. This system differs greatly from the Type "A" embodiment in the mechanism of action that abrades the skin since the Type "B" system uses a fluid media plus an abrading structure on the skin interface. Still several features of the Type "B" embodiment are similar to the Type "A" embodiment and the two modalities of treatment may be used to complement one another.

FIG. **6** shows that a hand-held instrument **208** has a removable working end **220** that defines a skin interface surface portion indicated at **225**. Handle portion **227***a* mates with housing **227***b*. A flexible tube **228** extends to a vacuum source **230**. A fluid reservoir **235** carrying a fluid skin treatment media is housed in the handle although it could also be a remote reservoir.

Referring now to FIGS. **7-9**, a first aperture arrangement consisting of at least one port or opening portion **240** of skin interface **225** that communicates with an interior passageway **242** that extends through housing **227***b* to hose **228** and the vacuum or negative (−) pressure source.

FIGS. **7-9** further show a second aperture arrangement in the skin interface consisting of at least one port or openings **250** that extend around an outer periphery of the skin interface **225**. These opening(s) of the second aperture arrangement are in fluid communication with the reservoir **235** and the treatment media therein. The skin interface has a series of primary ridge elements **255***a* and valley elements **255***b* together the secondary notches or grooves **260** as defined above with similar dimensional parameters. This embodiment differs however in that the apexes of ridge elements **255***a* are substantially a sharp edge as are the edged of the notches **260**. Thus, these primary surface elements **255***a* and secondary surface elements thereby define teeth therebetween that seem well suited to abrading skin layers particularly after being hydrated by the fluid source of the system. Experimentation has shown that the vacuum source and fluid source may be reversed between the first and second aperture arrangements **240** and **250** with the method of skin removal still working well. The vacuum system aspirates away skin debris and spent fluids as described previously. Of particular interest, the method of the invention appears to work well because the suction on the skin treatment site very quickly hydrated, or puffs up, the skin which in turn make the surface layer susceptible to painless abrasion. The ability of the system to rapidly deliver fluids to subsurface tissues allows the use of any pharmacological agent known in the art for enhancing skin rejuvenation as a part of the skin treatment. The system can use sterile water or saline solution for a treatment to remove dermal tissue with the abrasive surface of the treatment device. The system can also use a fluid carrying a chemical agent of a suitable concentration be selected from a group of acids including TCA (trichloroacetic acid), a glycolic acid including an alphahydroxy acid (AHA), a lactic acid, a citric acid, or phenol as disclosed in co-pending U.S. patent application Ser. No. 09/524,731 filed Mar. 14, 2000 which is incorporated herein by this reference.

Specific features of the invention may be shown in some figures and not in others, and this is for convenience only and any feature may be combined with another in accordance with the invention. While the principles of the invention have been made clear in the exemplary embodiments, it will be obvious to those skilled in the art that modifications of the structure, arrangement, proportions, elements, and materials may be utilized in the practice of the invention, and otherwise, which are particularly adapted to specific environments and operative requirements without departing from the principles of the invention. The appended claims are intended to cover and embrace any and all such modifications, with the limits only of the true purview, spirit and scope of the invention.

What is claimed is:

1. A method for treating a skin surface of a patient, comprising:

(a) applying against the skin surface of a patient an instrument body with a longitudinal axis and a distal working end, said distal working end comprising a working surface that carries an abrading structure comprising a plurality of sharp elements for engaging and abrading the skin surface together with a vacuum source coupled to at least one aperture about said working surface, the abrading structure and the at least one aperture positioned within a raised outer periphery that completely circumscribes the abrading structure and the at least one aperture;

(b) translating the working surface over the skin surface to thereby abrade the skin surface; and

(c) contemporaneously actuating the vacuum source to thereby cause suction engagement of the skin surface against the raised outer periphery and the plurality of sharp elements of the working surface and to aspirate skin debris through the at least one aperture.

2. The method as in claim **1** further comprising the step of providing a fluid to the skin to enhance suction engagement of the skin against the working surface.

3. The method as in claim **2** wherein the fluid is provided from a fluid source to a distal region of the instrument body.

4. The method as in claim **3** wherein the fluid is provided from a fluid source to at least one outflow port in the working surface.

5. The method as in claim **2** wherein the fluid is provided with a pharmacologically-active agent for treating skin.

6. The method as in claim **2** wherein the fluid is provided with an agent selected from the class consisting of citric acid and lactic acid.

7. The method as in claim **2** wherein the fluid is provided with an agent selected from the class comprising TCA (trichloroacetic acid), glycolic acid, alphahydroxy acid (AHA).

8. The method as in claim **2** wherein the fluid is provided with an acid for etching the skin surface.

9. The method as in claim **2** wherein the fluid is provided with a crystalline abrasive.

10. The method as in claim **1** wherein step (a) provides a working surface with undulations for increasing the area of the working surface for engaging skin.

11. A method for treating a skin surface of a patient, comprising:

translating a working surface of a handheld device relative to the skin surface, said working surface comprising an abrasive structure configured to abrade the skin surface, an aperture in the working surface, an outer periphery that encircles the abrasive structure and the aperture, at least a portion of the abrasive structure spaced from the aperture; and

continuously applying a vacuum through the aperture formed in the working surface in order to draw the skin

against the outer periphery and the abrasive structure and aspirate debris away from the working surface while abrading the skin surface.

12. The method as in claim **11**, further comprising the step of providing a fluid to the skin, said providing a fluid occurring while the skin surface is being abraded.

13. The method as in claim **12**, wherein providing a fluid to the skin surface comprises supplying at least one fluid through a fluid opening located at or near the working surface of the handheld device.

14. The method as in claim **12** wherein the fluid comprises a pharmacologically-active agent.

15. A method for treating human skin, comprising:

translating a handheld device relative to a skin surface to abrade said skin surface, said handheld device comprising a working surface with an abrasive structure at a distal end of said handheld device and at least one aperture at or near the working surface, said abrasive structure and said at least one aperture being circumscribed by an outer periphery of the working surface, and the at least one aperture being positioned radially closer to the outer periphery than said abrasive structure, said aperture being in fluid communication with a vacuum source to remove debris away from the working surface;

abrading the skin surface by translating the abrading structure over the skin surface; and

continuously aspirating debris through the at least one aperture while the skin surface is being abraded.

16. The method as in claim **15**, further comprising the step of providing a fluid toward the working surface.

* * * * *

EXHIBIT 4

Knobbe Martens Olson & Bear LLP
Intellectual Property Law

2040 Main Street
Fourteenth Floor
Irvine, CA 92614
Tel 949-760-0404
Fax 949-760-9502
www.kmob.com

Rabinder N. Narula
rnarula@kmob.com

April 15, 2011
VIA FEDERAL EXPRESS

David Suzuki
President
Bio-Therapeutic, Inc.
2244 1st Ave. S.
Seattle, WA 98134

Re: **Edge Systems' Intellectual Property**
Our Reference: EDGE.064IS

Dear Mr. Suzuki:

We represent Edge Systems, Inc. in connection with certain intellectual property law matters. Edge Systems has expended considerable time, effort and money to develop its proprietary skin resurfacing instrumentation and methodology. This includes its Hydrafacial™ and Delphia™ Microdermabrasion systems, as well as products still in the development process.

To protect its substantial investment, Edge Systems has the rights to various patents and patent applications throughout the world. These include United States Patent No. 6,299,620 and 6,641,591, as well as recently-issued U.S. Patent Nos. 7,678,120 and 7,789,886. Copies of these patents are enclosed as *Exhibit A* to this letter. In addition, please note that Edge Systems has rights in additional pending patent applications, both within and outside the U.S., that are generally directed to skin resurfacing technologies.

As you can appreciate, the patents discussed above provide Edge Systems with exclusive rights to, *inter alia*, systems and methods of treating skin that comprise an instrument with a working surface for abrading the skin and an opening in the working surface that is coupled to a vacuum source.

It is our understanding that Bio-Therapeutic, Inc. currently sells microdermabrasion systems, marketed under the trade names "Bio-Hydroderm™," "Bio-Hydrotip™," and "AQUAFUSE." Based on our review of the publicly available information describing these systems, we conclude that, at a minimum, the patents listed above warrant your immediate attention.

Knobbe Martens Olson & Bear LLP

In light of the above, we are certain that you can appreciate the need to evaluate whether it is in the best interest of Bio-Therapeutic, Inc. to immediately cease the manufacture and supply of the afore-mentioned microdermabrasion systems. We look forward to hearing from you within three (2) weeks.

Best regards,

Rabinder N. Narula

Enclosures

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041511

EXHIBIT 5

Knobbe Martens Olson & Bear LLP
Intellectual Property Law

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May 19, 2011
VIA FEDERAL EXPRESS

David Suzuki
President
Bio-Therapeutic, Inc.
2244 1st Ave. S.
Seattle, WA 98134

Re: **Edge Systems' Intellectual Property**
Our Reference: EDGE.064IS

Dear Mr. Suzuki:

I am writing to follow-up on my letter of April 15, 2011 (enclosed). In my letter, I indentified several United States Patents that relate, *inter alia*, to systems and methods of treating skin that comprise an instrument with a working surface for abrading the skin and an opening in the working surface that is coupled to a vacuum source.

As you are probably aware, there can be significant risk to Genesis Bio-Therapeutic and its customers if it chooses to ignore the patent rights of others. For example, under the United States Patent Laws, an infringer is liable for damages in the amount of the patent owner's lost profits, and, in any event, no less than a reasonable royalty. *See* 35 U.S.C. §284. Bio-Therapeutic and/or its customers may also be permanently enjoined from making, using, offering to sell or selling devices covered by the enclosed patent. *See* 35 U.S.C. §283. In patent litigation, the court may additionally require an infringer to pay the attorneys fees expended by the patent owner. *See* 35 U.S.C. §285. These attorneys fees can even exceed the total damages awarded. Bio-Therapeutic may further face the additional risk of enhanced liability and "treble damages" if it knowingly chooses to ignore the patent rights of others.

Accordingly, this matter warrants your immediate attention. If you have forwarded this matter to your patent attorney, please send me his contact information so that I can contact him directly. We look forward to hearing from you within one (1) week.

Best regards,

Rabinder N. Narula

Enclosures

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UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

NOTICE OF ASSIGNMENT TO UNITED STATES MAGISTRATE JUDGE FOR DISCOVERY

This case has been assigned to District Judge John F. Walter and the assigned discovery Magistrate Judge is Alicia G. Rosenberg.

The case number on all documents filed with the Court should read as follows:

CV11- 4993 JFW (AGRx)

Pursuant to General Order 05-07 of the United States District Court for the Central District of California, the Magistrate Judge has been designated to hear discovery related motions.

All discovery related motions should be noticed on the calendar of the Magistrate Judge

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NOTICE TO COUNSEL

A copy of this notice must be served with the summons and complaint on all defendants (if a removal action is filed, a copy of this notice must be served on all plaintiffs).

Subsequent documents must be filed at the following location:

[X] **Western Division** **312 N. Spring St., Rm. G-8** **Los Angeles, CA 90012**	[ ] **Southern Division** **411 West Fourth St., Rm. 1-053** **Santa Ana, CA 92701-4516**	[ ] **Eastern Division** **3470 Twelfth St., Rm. 134** **Riverside, CA 92501**

Failure to file at the proper location will result in your documents being returned to you.

AO 440 (Rev. 12/09) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

Central District of California

EDGE SYSTEMS CORPORTION, a California corporation, and AXIA MEDSCIENCES, LLC, a Delaware limited liability company,

Plaintiff

v.

BIO-THERAPEUTIC, INC., a Washington corporation,

Defendant

Civil Action No. CV 11-04993 JFW (AGRx)

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* BIO-THERAPEUTIC, INC.
2244 1st Avenue S.
Seattle, Washington 98134

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are: Brenton R. Babcock
2040 Main Street, Suite 1400
Irvine, CA 92614

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

CLERK OF COURT

Date: JUN 13 2011

NANCY [illegible]

Signature of Clerk or Deputy

1191

UNITED STATES DISTRICT COURT, CENTRAL DISTRICT OF CALIFORNIA
CIVIL COVER SHEET

I (a) PLAINTIFFS (Check box if you are representing yourself ☐)
EDGE SYSTEMS CORPORATION, a California corporation, AXIA MEDSCIENCES, LLC, a Delaware limited liability company,

DEFENDANTS
BIO-THERAPEUTIC, INC., a Washington corporation.

(b) Attorneys (Firm Name, Address and Telephone Number. If you are representing yourself, provide same.)
Brenton R. Babcock (Bar No. 162,120); Kent N. Shum (Bar No. 259,189)
KNOBBE, MARTENS, OLSON & BEAR, LLP
2040 Main Street, 14th Floor, Irvine, CA 92614; (949) 760-0404

Attorneys (If Known)

II. BASIS OF JURISDICTION (Place an X in one box only.)

☐ 1 U.S. Government Plaintiff
☑ 3 Federal Question (U.S. Government Not a Party)
☐ 2 U.S. Government Defendant
☐ 4 Diversity (Indicate Citizenship of Parties in Item III)

III. CITIZENSHIP OF PRINCIPAL PARTIES - For Diversity Cases Only
(Place an X in one box for plaintiff and one for defendant.)

	PTF	DEF		PTF	DEF
Citizen of This State	☐ 1	☐ 1	Incorporated or Principal Place of Business in this State	☐ 4	☐ 4
Citizen of Another State	☐ 2	☐ 2	Incorporated and Principal Place of Business in Another State	☐ 5	☐ 5
Citizen or Subject of a Foreign Country	☐ 3	☐ 3	Foreign Nation	☐ 6	☐ 6

IV. ORIGIN (Place an X in one box only.)

☑ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from another district (specify): ☐ 6 Multi-District Litigation ☐ 7 Appeal to District Judge from Magistrate Judge

V. REQUESTED IN COMPLAINT: **JURY DEMAND:** ☑ Yes ☐ No (Check 'Yes' only if demanded in complaint.)

CLASS ACTION under F.R.C.P. 23: ☐ Yes ☑ No ☐ **MONEY DEMANDED IN COMPLAINT: $** To be determined at trial

VI. CAUSE OF ACTION (Cite the U.S. Civil Statute under which you are filing and write a brief statement of cause. Do not cite jurisdictional statutes unless diversity.)

VII. NATURE OF SUIT (Place an X in one box only.)

OTHER STATUTES
☐ 400 State Reapportionment
☐ 410 Antitrust
☐ 430 Banks and Banking
☐ 450 Commerce/ICC Rates/etc.
☐ 460 Deportation
☐ 470 Racketeer Influenced and Corrupt Organizations
☐ 480 Consumer Credit
☐ 490 Cable/Sat TV
☐ 810 Selective Service
☐ 850 Securities/Commodities/ Exchange
☐ 875 Customer Challenge 12 USC 3410
☐ 890 Other Statutory Actions
☐ 891 Agricultural Act
☐ 892 Economic Stabilization Act
☐ 893 Environmental Matters
☐ 894 Energy Allocation Act
☐ 895 Freedom of Info. Act
☐ 900 Appeal of Fee Determination Under Equal Access to Justice
☐ 950 Constitutionality of State Statutes

CONTRACT
☐ 110 Insurance
☐ 120 Marine
☐ 130 Miller Act
☐ 140 Negotiable Instrument
☐ 150 Recovery of Overpayment & Enforcement of Judgment
☐ 151 Medicare Act
☐ 152 Recovery of Defaulted Student Loan (Excl. Veterans)
☐ 153 Recovery of Overpayment of Veteran's Benefits
☐ 160 Stockholders' Suits
☐ 190 Other Contract
☐ 195 Contract Product Liability
☐ 196 Franchise

REAL PROPERTY
☐ 210 Land Condemnation
☐ 220 Foreclosure
☐ 230 Rent Lease & Ejectment
☐ 240 Torts to Land
☐ 245 Tort Product Liability
☐ 290 All Other Real Property

TORTS
PERSONAL INJURY
☐ 310 Airplane
☐ 315 Airplane Product Liability
☐ 320 Assault, Libel & Slander
☐ 330 Fed. Employers' Liability
☐ 340 Marine
☐ 345 Marine Product Liability
☐ 350 Motor Vehicle
☐ 355 Motor Vehicle Product Liability
☐ 360 Other Personal Injury
☐ 362 Personal Injury-Med Malpractice
☐ 365 Personal Injury-Product Liability
☐ 368 Asbestos Personal Injury Product Liability

IMMIGRATION
☐ 462 Naturalization Application
☐ 463 Habeas Corpus-Alien Detainee
☐ 465 Other Immigration Actions

TORTS
PERSONAL PROPERTY
☐ 370 Other Fraud
☐ 371 Truth in Lending
☐ 380 Other Personal Property Damage
☐ 385 Property Damage Product Liability

BANKRUPTCY
☐ 422 Appeal 28 USC 158
☐ 423 Withdrawal 28 USC 157

CIVIL RIGHTS
☐ 441 Voting
☐ 442 Employment
☐ 443 Housing/Accommodations
☐ 444 Welfare
☐ 445 American with Disabilities - Employment
☐ 446 American with Disabilities - Other
☐ 440 Other Civil Rights

PRISONER PETITIONS
☐ 510 Motions to Vacate Sentence Habeas Corpus
☐ 530 General
☐ 535 Death Penalty
☐ 540 Mandamus/ Other
☐ 550 Civil Rights
☐ 555 Prison Condition

FORFEITURE / PENALTY
☐ 610 Agriculture
☐ 620 Other Food & Drug
☐ 625 Drug Related Seizure of Property 21 USC 881
☐ 630 Liquor Laws
☐ 640 R.R. & Truck
☐ 650 Airline Regs
☐ 660 Occupational Safety /Health
☐ 690 Other

LABOR
☐ 710 Fair Labor Standards Act
☐ 720 Labor/Mgmt. Relations
☐ 730 Labor/Mgmt. Reporting & Disclosure Act
☐ 740 Railway Labor Act
☐ 790 Other Labor Litigation
☐ 791 Empl. Ret. Inc. Security Act

PROPERTY RIGHTS
☐ 820 Copyrights
☑ 830 Patent
☐ 840 Trademark

SOCIAL SECURITY
☐ 861 HIA (1395ff)
☐ 862 Black Lung (923)
☐ 863 DIWC/DIWW (405(g))
☐ 864 SSID Title XVI
☐ 865 RSI (405(g))

FEDERAL TAX SUITS
☐ 870 Taxes (U.S. Plaintiff or Defendant)
☐ 871 IRS-Third Party 26 USC 7609

FOR OFFICE USE ONLY: Case Number: CV 11-04993 JFW (AGRx)

AFTER COMPLETING THE FRONT SIDE OF FORM CV-71, COMPLETE THE INFORMATION REQUESTED BELOW.

UNITED STATES DISTRICT COURT, CENTRAL DISTRICT OF CALIFORNIA
CIVIL COVER SHEET

VIII(a). IDENTICAL CASES: Has this action been previously filed in this court and dismissed, remanded or closed? ☑ No ☐ Yes
If yes, list case number(s): _____

VIII(b). RELATED CASES: Have any cases been previously filed in this court that are related to the present case? ☑ No ☐ Yes
If yes, list case number(s): _____

Civil cases are deemed related if a previously filed case and the present case:
(Check all boxes that apply) ☐ A. Arise from the same or closely related transactions, happenings, or events; or
☐ B. Call for determination of the same or substantially related or similar questions of law and fact; or
☐ C. For other reasons would entail substantial duplication of labor if heard by different judges; or
☐ D. Involve the same patent, trademark or copyright, and one of the factors identified above in a, b or c also is present.

IX. VENUE: (When completing the following information, use an additional sheet if necessary.)

(a) List the County in this District; California County outside of this District; State if other than California; or Foreign Country, in which **EACH** named plaintiff resides.
☐ Check here if the government, its agencies or employees is a named plaintiff. If this box is checked, go to item (b).

County in this District:*	California County outside of this District; State, if other than California; or Foreign Country
Los Angeles	

(b) List the County in this District; California County outside of this District; State if other than California; or Foreign Country, in which **EACH** named defendant resides.
☐ Check here if the government, its agencies or employees is a named defendant. If this box is checked, go to item (c).

County in this District:*	California County outside of this District; State, if other than California; or Foreign Country
King County	

(c) List the County in this District; California County outside of this District; State if other than California; or Foreign Country, in which **EACH** claim arose.
Note: In land condemnation cases, use the location of the tract of land involved.

County in this District:*	California County outside of this District; State, if other than California; or Foreign Country
Los Angeles	

*** Los Angeles, Orange, San Bernardino, Riverside, Ventura, Santa Barbara, or San Luis Obispo Counties**
Note: In land condemnation cases, use the location of the tract of land involved

X. SIGNATURE OF ATTORNEY (OR PRO PER): _____ Date 6/13/11

Notice to Counsel/Parties: The CV-71 (JS-44) Civil Cover Sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law. This form, approved by the Judicial Conference of the United States in September 1974, is required pursuant to Local Rule 3-1 is not filed but is used by the Clerk of the Court for the purpose of statistics, venue and initiating the civil docket sheet. (For more detailed instructions, see separate instructions sheet.)

Key to Statistical codes relating to Social Security Cases:

Nature of Suit Code	Abbreviation	Substantive Statement of Cause of Action
861	HIA	All claims for health insurance benefits (Medicare) under Title 18, Part A, of the Social Security Act, as amended. Also, include claims by hospitals, skilled nursing facilities, etc., for certification as providers of services under the program. (42 U.S.C. 1935FF(b))
862	BL	All claims for "Black Lung" benefits under Title 4, Part B, of the Federal Coal Mine Health and Safety Act of 1969. (30 U.S.C. 923)
863	DIWC	All claims filed by insured workers for disability insurance benefits under Title 2 of the Social Security Act, as amended; plus all claims filed for child's insurance benefits based on disability. (42 U.S.C. 405(g))
863	DIWW	All claims filed for widows or widowers insurance benefits based on disability under Title 2 of the Social Security Act, as amended. (42 U.S.C. 405(g))
864	SSID	All claims for supplemental security income payments based upon disability filed under Title 16 of the Social Security Act, as amended.
865	RSI	All claims for retirement (old age) and survivors benefits under Title 2 of the Social Security Act, as amended. (42 U.S.C. (g))